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PATENT
Attorney Docket No. 101.0023-04000
Customer No. 22882

JRW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Confirmation No. 3041
Gary Karlin Michelson, M.D.)
Serial No.: 08/354,450) Group Art Unit: 3764
Filed: December 12, 1994) Examiner: D. DeMille
For: DEVICE FOR ARTHROSCOPIC)
MENISCAL REPAIR)

Mail Stop PETITIONS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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1. Petition Under 37 C.F.R. § 1.181(A) with Exhibits A-C
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PATENT

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Sir:

PETITION UNDER 37 C.F.R. § 1.181(a)

In response to the Examiner's Answer dated July 1, 2005 (the "Examiner's Answer"), Appellant petitions the Commissioner to send Appellant a corrected Examiner's Answer designating the following as new grounds of rejection: (1) the rejection of independent claim 144 under 35 U.S.C. § 112, first paragraph, as not being supported in the specification as originally filed relative to the phrase "at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees;" (2) the rejection of claim 192 under 35 U.S.C. § 103(a) over U.S. Patent No. 5,261,914 to Warren ("Warren") in view of U.S. Patent No. 4,548,202 to Duncan ("Duncan"); and (3) the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph.

I. Background.

The above-identified application is on appeal from an Office Action dated March 19, 2004 (the "March 2004 Office Action"). Appellant filed an Appeal Brief on April 20, 2005 (the "Appeal Brief"). An Examiner's Answer was mailed July 1, 2005 (the "Examiner's Answer"). In the Examiner's Answer, the Examiner raised three new grounds of rejection.

In the March 2004 Office Action, a copy of which is attached hereto as Exhibit A, the Examiner rejected claims 29-300 under 35 U.S.C. § 112, first paragraph, as

containing subject matter which was not adequately described as set forth in the objection to the specification under 35 U.S.C. § 112, first paragraph. For the objection to the specification under 35 U.S.C. § 112, first paragraph, the Examiner stated that “[t]here appears to be no support in the specification for the above noted language or the criticality why this is now being claimed.” (March 2004 Office Action, page 3, paragraph 2). The “above noted language” referred to by the Examiner is contained in the objection to the Amendment filed January 7, 2004 under 35 U.S.C. § 132 as introducing new matter into the specification. The Examiner’s new matter objection listed 12 phrases from the claims which the Examiner contended was new matter. (March 2004 Office Action, page 2, paragraph 1). Among the phrases objected to by the Examiner is the phrase “at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees,” as recited in dependent claim 145.

The Examiner rejected dependent claim 192, among other claims, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,261,914 to Warren. Claim 192 recites the tissue rivet of independent claim 176 and dependent claim 187 having a plurality of projections positioned in a radially staggered configuration along the shaft of the tissue rivet. The Examiner’s rejection did not provide any rationale specific to the subject matter of claim 192.

The March 2004 Office Action also did not contain any objection to the specification under 35 U.S.C. § 112, first paragraph, as not complying with the enablement requirement.

In the Appeal Brief, Appellant traversed the Examiner’s new matter objection, objection to the specification under 35 U.S.C. § 112, first paragraph, and the claim rejection under 35 U.S.C. § 112, first paragraph, as they related to the phrase “at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees,” as recited in dependent claim 145. (Appeal Brief, pages 11-13, 16, and 17). A copy of the Appeal Brief is attached hereto as Exhibit B.

Appellant explained in the Appeal Brief that Warren did not teach or suggest the subject matter of claim 192, and that the Examiner did not provide any grounds and/or

motivation for the rejection specific to the subject matter of claim 192. (Appeal Brief, page 27).

In the Examiner's Answer, the Examiner maintained the objections and rejection to the phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees," as recited in dependent claim 145. (Examiner's Answer, page 5, paragraph 1). A copy of the Examiner's Answer is attached hereto as Exhibit C. In addition to maintaining his positions, the Examiner stated "[t]he parent claim 144 recites the first portion of the flexible member forms an included angle greater than 90 degrees that likewise is not contingent on when the device is in use. Likewise this limitation is not supported by the disclosure as originally filed." (Examiner's Answer, page 5, paragraph 1). Appellant respectfully submits that the Examiner's further rejection of claim 144 constitutes a new ground of rejection.

The Examiner also stated that "[r]egarding Appellant's arguments in paragraph V subparagraph B9, Duncan teaches the plurality of projections in radially staggered configuration as claimed and would have been an obvious provision in Warren. There is no unobviousness to the exact shape of the projections as long as they prevent removal of the fastener." (Examiner's Answer, page 20, paragraph 3). Appellant respectfully submits that the Examiner's new combination of Warren in view of Duncan to reject claim 192 constitutes a new ground of rejection.

The Examiner further stated that "[t]he specification doesn't appear to provide such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." (Examiner's Answer, page 12, paragraph 2). Appellant respectfully submits that the Examiner's enablement rejection constitutes a new ground of rejection.

II. Arguments.

Appellant submits that the Examiner's Answer raised three new grounds of rejection. According to information posted by the Office in the Board of Patent Appeals and Interferences section of the United States Patent & Trademark Office website, the Appellant is permitted to seek the TC Director's supervisory review of the Examiner's Answer when the Appellant alleges that a rejection in an Examiner's Answer is a new

ground of rejection, but the Examiner did not designate the rejection as a new ground of rejection. (BPAI FAQ-Rules of Practice before the BPAI (effective 13SEP2004), Section F, question 5, accessible at www.uspto.gov/web/offices/dcom/bpai/fr2004/bpaifaq.html (August 26, 2005)). Additionally, “[i]f the TC Director or designee decides that the rejection is considered a new ground of rejection, the examiner would be required to send a corrected examiner’s answer that identifies the rejection as a new ground of rejection in a separate examiner’s answer and include the approval of the TC Director or designee.” (BPAI FAQ-Rules of Practice before the BPAI (effective 13SEP2004), Section F, question 5 (August 26, 2005).

- A. The new ground of rejection of independent claim 144 under 35 U.S.C. § 112, first paragraph as not being supported in the specification as originally filed relative to the phrase “at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees.”

In the Examiner’s Answer, the Examiner stated that the limitation in independent claim 144 where “the first portion of the flexible member forms an included angle greater than 90 degrees” is also “not supported by the disclosure as originally filed.” (Examiner’s Answer, page 5, paragraph 1). This phrase was not previously rejected by the Examiner in the March 2004 Office Action. Appellant respectfully submits that the Examiner’s rejection under 35 U.S.C. § 112, first paragraph, of the phrase “at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees” as recited in independent claim 144 constitutes a new ground of rejection which requires the approval of the TC Director or designee as outlined by the procedure set forth in the “BPAI FAQ-Rules of Practice before the BPAI.”

- B. The new ground of rejection of dependent claim 192 under 35 U.S.C. § 103(a) over Warren in view of Duncan.

In the Examiner’s Answer, the Examiner replied to Appellant’s remarks that Warren did not teach or suggest the subject matter of claim 192 by incorporating for the first time the teachings of Duncan into the rejection that was previously over Warren alone. (See Examiner’s Answer, page 20, paragraph 3). Appellant respectfully submits that the Examiner’s combination of Duncan with Warren to reject claim 192 constitutes

a second new ground of rejection which requires the approval of the TC Director or designee as outlined by the procedure set forth in the “BPAI FAQ-Rules of Practice before the BPAI.”

C. The new ground of rejection concerning the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph.

In the Examiner’s Answer, while addressing Appellant’s remarks with respect to the Examiner’s new matter objection under 35 U.S.C. § 132, the Examiner stated that “[t]he specification doesn’t appear to provide such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” (Examiner’s Answer, page 12, paragraph 2). The language quoted by the Examiner corresponds to the language from Form paragraph 7.31.02 “Rejection, 35 U.S.C. 112, 1st Paragraph, Enablement.” (MPEP § 706.03(c); see also, MPEP § 2164.01 “Test of Enablement” (May 2004)). The March 2004 Office Action did not contain an objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph. Accordingly, Appellant submits that the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph, constitutes a third new ground of rejection which requires the approval of the TC Director or designee as outlined by the procedure set forth in the “BPAI FAQ-Rules of Practice before the BPAI.”

Appellant respectfully submits that Appellant has not had a fair opportunity to address the Examiner’s new rejections while being under a non-final condition for submitting a response. Designating each of the following: (1) the rejection of claim 144 under 35 U.S.C. § 112, first paragraph, as not being supported in the specification as originally filed relative to the phrase “at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees;” (2) the rejection of claim 192 under 35 U.S.C. § 103(a) over Warren in view of Duncan; and (3) the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph, as new grounds of rejection will permit Appellant the opportunity to pursue of one of the options listed under 37 C.F.R. § 41.39(b).

III. Conclusion.

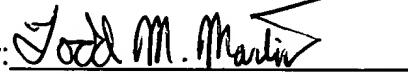
In view of the above remarks, Applicant respectfully requests the Commissioner to send Appellant a corrected Examiner's Answer designating: (1) the rejection of independent claim 144 under 35 U.S.C. § 112, first paragraph, as not being supported in the specification as originally filed relative to the phrase "at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees;" (2) the rejection of claim 192 under 35 U.S.C. § 103(a) over Warren in view of Duncan; and (3) the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph, as new grounds of rejection.

If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: September 1, 2005

By: 

Todd M. Martin
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O P E I A P G
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EXHIBIT A

101.0003-04

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 08/354,450 | 12/12/1994 | GARY K. MICHELSON | P10936V | 3041 |
| 22882 | 7590 | 03/19/2004 | | EXAMINER |
| MARTIN & FERRARO, LLP 1557 LAKE O' PINES STREET, NE HARTVILLE, OH 44632 | | | DEMILLE, DANTON D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3764 | |

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

MAR 22 2004

MARTIN & FERRARO LLP

DOCKETED BY: Jm
ON: 3-24-04
ACTION
REQUIRED: rsp

DATE REQUIRED: 6-19-04

L/D 9-19-04



| | | |
|-----------------|--------------------|--|
| Application No. | Applicant(s) | |
| 08/354,450 | MICHELSON, GARY K. | |
| Examiner | Art Unit | |
| Danton DeMille | 3764 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 January 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 29-300 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 29-300 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Specification***

The amendment filed 07 January 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in the claims it is recited that a) said flexible member being at least in part curved b) said flexible member is deformable to have an at least in part concave shape c) said flexible member has a greater surface area to mass ratio than said shaft d) said flexible member has a smaller mass than the mass of said shaft e) said flexible projections are oriented in at least two arrays along the mid-longitudinal axis of said shaft f) said flexible projections are oriented in at least four arrays along the mid-longitudinal axis of said shaft g) at least two of said flexible projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft h) said rivet has a length of approximately 10 mm i) at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees j) the outer perimeter remains substantially in a single plane when moving relative to said shaft k) at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft l) at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft.

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

There appears to be no support in the specification for the above noted language or the criticality why this is now being claimed.

Claims 29-300 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not adequately described as set forth in the above objection to the specification.

Claim Rejections - 35 USC § 112

Claims 29-300 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There doesn't appear to be any support in the specification for the language noted above in the objection to the specification. For example, it is not clear how much weight can be given the language that the flexible projections are oriented in at least two arrays along the mid-longitudinal axis of the shaft when there is no disclosure for such structure. Applicant is using the language "along the mid-longitudinal axis of the shaft to mean along the length of the shaft. As understood there are no plural arrays of projections that run along the length of the shaft. There are plural arrays that run "around" the mid-longitudinal axis of the shaft but not "along" the shaft.

There also doesn't appear to be support for at least two of the flexible projections to extend in the same plane transverse to the axis of the shaft. As understood the projections extend

at an angle "slightly sloped away from the projection head 14" (paragraph spanning pages 5-6 of this disclosure). If the projections extend at an angle to the shaft then it would be impossible for an adjacent projection to extend in the same plane.

The rivet is also not disclosed as being approximately 10 mm in length. It is disclosed as being approximately 8 mm in length.

The flexible member is also not disclosed as being part curved or part concave or at an angle not perpendicular to the longitudinal axis of the shaft.

To any extent the claims are understood and appear to be supported by a clear and complete disclosure the following appears to be appropriate.

Claim Rejections - 35 USC § 103

Claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warren.

Warren discloses the same surgical rivet arrangement as that claimed by appellant. He discloses that the rivet has a hollow shaft and a number of flexible projections extending from said shaft and the flexible member at the other end. He also discloses that the rivet is made of biodegradable material, copolymers of glycolide, the same material used by appellant. Warren also teaches that the material is intended to be resilient such that the projections deform upon insertion (column 6, lines 1-6). Due to the fact that the rivet of Warren is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that rivet of Warren would comprehend the claimed resilient characteristic at least

to some extent. It is not clear exactly how the claimed rivet is different from Warren's rivet. The only difference between the claims and Warren's device is that the claims recite that the flexible head member deforms when it is pounded into place. Inherently any head member made of a polymeric material when pounded into place on a surface that is curved or irregular will deform at least to a certain extent. The 2.5 mm size of the polymeric rivet would also yield a degree of flexibility to the rivet. As the rivet is being forced into the bone the head will come into contact with the first portion of the bone it meets and as the rivet continues to be forced into the bone other portions of the head will then come into contact with the bone. Because different portions of the head will come into contact with the bone at different times the head will deform as one portion of the head cannot move and other portions continue to move closer to the bone. The resulting head portion will deform at least to some extent. It would appear that the fastener of Warren comprehends the claims since all of the positive structural limitations are met. The intended use of the rivet deforming in use would also appear to be comprehended by the structure of Warren.

Warren teaches "the dimensions of the fastener could be changed so as to make the fastener longer and thinner, or shorter and fatter, etc." column 6, lines 46-49. Warren goes further to state, "for other purposes (e.g., for attaching ligaments to bones in the leg region), other dimensions may be more desirable." Clearly the dimensions and relative sizes can be modified dependent on practical intended use considerations. Warren teaches that the fastener can be thinner. If the device is intended to be used in softer tissue then the thickness of the fastener can be reduced. A thinner fastener would make a more flexible fastener. Softer tissue would require the projections to be a little longer to more securely engage the softer tissue. The

specific dimensions used for a specific intended use are well within the realm of the artisan of ordinary skill. Such considerations are obvious to one of ordinary skill in the art and not a patentable distinction. This thinner fastener would then result in a head member that would flex as it is forced into contact with the bone. To any extent it is felt that the structure of Warren is not flexible enough to flex during use, it would have been obvious to modify the rivet of Warren as taught by Warren to find the desired dimensions of a specific intended use that would be thin enough that would result in a head that flexes during implantation.

Moreover, making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art. As the skin moves over the head of the fastener the skin can become irritated. Reducing the size of the head would provide a smooth transfer surface, thereby insuring that nothing would be caught on the extending rivet head and damaged. Making the head of screws, rivets and the like flush has always been a problem solved through routine experimentation.

Claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, 256-300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bays et al. in view of Warren. Bays teaches another fastener that has all of the claimed structure including being made out of the same material as the instant invention. For the same reasons as above, it is not clear how the claimed invention would define over Bays other than how it deforms during use. It would appear the rivet of Bays comprehends the claims including the flexible head member being "adapted so as to conform to the surface of the tissue in which said rivet is inserted, said flexible member being at least in part curved when said flexible member is in contact with the tissue". If the area of the bone where the rivet is

being inserted is curved then the head member would be pressed against the curved surface and deform to match the same shape at least to a certain extent. The same structure made of the same material would appear to comprehend the claimed invention.

Bays teaches the rivet is approximately 8 mm long. As noted above, the specific dimensions of the rivet are well within the realm of the artisan of ordinary skill. It would have been obvious to modify Bays to dimension the rivet to fit any specific intended use desired. To any extent it is felt that the structure of Bays is not flexible enough to flex during use, it would have been obvious to modify the rivet of Bays as taught by Warren to find the desired dimensions of a specific intended use that would be thin enough resulting in a head that flexes during implantation as noted above.

Claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above, and further in view of Duncan, Chisholm et al. or Paravano.

There is no unobviousness to the specific shape or number of ribs on the shaft of the rivet. Both Bays and Warren teach that the specific configuration of the ribs is well within the artisan of ordinary skill. Warren teaches column 7, lines 3+ “that surgical fastener 100 might be formed with more or less ribs 135 than the three ribs shown in FIGS. 1-8. Thus, for example, a surgical fastener 100A having eight ribs 135A is shown in FIGS. 9-11.” Bays teaches column 4, lines 62-64, “As few as one and more than three barb members may be provided within the scope of the present invention, so long as the barb member or members provide sufficient resistance to rearward movement of the shaft portion through the cartilaginous tissue.” Duncan, Chisholm and Paravano are all cited to show different conventional alternative arrangements of ribs on the

shafts of fasteners. Duncan teaches a surgical fastener that has barbs that are spaced in plural arrays around the axis of the shaft. Chisholm and Paravano also exemplify the art of providing plural arrays of barbs or fins spaced around the axis of the shaft. It would have been obvious to one of ordinary skill in the art to further modify the prior art to arrange the ribs, fins or barbs in arrays around the axis of the shaft as taught by Duncan, Chisholm or Paravano to provide the desired level of anchorage for the fastener to hold it in place.

Claims 87, 88, 131, 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above, and further in view of Simons.

There appears to be no unobviousness to exactly how the rivet interfaces with the driving element. The driving element of the rivet merely has to drive the rivet into the bone. Warren teaches a hollow driver 600 that buts the end of the rivet to force the rivet into the hole in the bone. Bays teaches a driver that includes a shaft that mates with a passageway within the rivet. There is no unobviousness to how the driver forces the rivet into the bone. Simons teaches another equivalent way for the driver to mate with the head of the fastener. The fastener includes a generally spherical recess in the head. It would have been obvious to one of ordinary skill in the art to further modify the prior art to use a spherical recess and cooperating driver as taught by Simons as an obvious equivalent way of mating the driver to the fastener to force the fastener into place.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3764

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

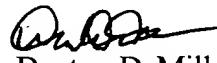
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13 March, 2004

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|-----------------------------------|-------------------------|---|-------------|
| Notice of References Cited | Application/Control No. | Applicant(s)/Patent Under Reexamination | |
| | 08/354,450 | MICHELSON, GARY K. | |
| | Examiner | Art Unit | Page 1 of 1 |
| Danton DeMille | 3764 | | |

U.S. PATENT DOCUMENTS

| * | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | Classification |
|---|--|-----------------|--------------|----------------|
| A | US-4,338,835 | 07-1982 | Simons, Leon | 81/436 |
| B | US- | | | |
| C | US- | | | |
| D | US- | | | |
| E | US- | | | |
| F | US- | | | |
| G | US- | | | |
| H | US- | | | |
| I | US- | | | |
| J | US- | | | |
| K | US- | | | |
| L | US- | | | |
| M | US- | | | |

FOREIGN PATENT DOCUMENTS

| * | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Country | Name | Classification |
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| N | | | | | |
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NON-PATENT DOCUMENTS

| * | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
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| U | |
| V | |
| W | |
| X | |

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.





EXHIBIT B

PATENT

Attorney Docket No. 101.0023-04000

Customer No. 22882

APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)
Gary Karlin Michelson, M.D.)
Serial No.: 08/354,450) Group Art Unit: 3764
Filed: December 12, 1994) Examiner: D. DeMille
For: DEVICE FOR ARTHROSCOPIC)
MENISCAL REPAIR)

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF

Real Party in Interest

The real party in interest is Gary Karlin Michelson, M.D. (hereinafter, the "Appellant").

Related Appeals and Interferences

There are no appeals or interferences pending which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 1-28 have been cancelled.

Claims 29-300 are pending.

Claims 29-300 have been rejected and are being appealed.

Status of Amendments

An amendment under 37 C.F.R. § 1.116 dated September 20, 2004 (the "September 2004 Amendment") was entered by the Examiner in the Advisory Action dated November 4, 2004 (the "November 2004 Advisory Action").

Summary of Claimed Subject Matter

Independent claim 29.

The present invention in one preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together and preventing movement of rivet 100 in the tissue. Rivet 100 is made of a bioabsorbable material (Specification, page 6, lines 27-31), and comprises a shaft 112 (Specification, page 7, lines 6-8; Fig. 5) having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has a maximum cross-sectional dimension transverse to the mid-longitudinal axis (Fig. 5), a truncated conical penetration head 114 (Specification, page 7, lines 1 and 2; Fig. 5) at the leading end, and a flexible member 118 (Specification, page 7, line 6; Fig. 5) at trailing end 120. Flexible member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, and a dimension larger than the maximum cross-sectional dimension of shaft 112. Flexible member 118 is adapted to deform so as to conform to the surface of the tissue in which the rivet is inserted. (Specification, page 6, lines 31-33). Flexible member 118 is at least in part curved when flexible member 118 is in contact with the tissue M (Fig. 2; the meniscus is curved (see Exhibit A), thus the flexible member is curved when in contact with the tissue of the meniscus). Shaft 112 has a plurality of flexible projections 116 (Specification, page 7, lines 2-5; Fig. 5) extending radially from shaft 112. Flexible projections 116 are separate and spaced apart from one another (Fig. 5). At least one of flexible projections 116 is capable of flexing (Specification, page 6, line 27) toward shaft 112 when being inserted in the tissue (Fig. 7).

Independent claim 60.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 is made of a bioabsorbable material (Specification, page 6, lines 27-31), and comprises a shaft 112 (Specification, page 7, lines 6-8; Fig. 5) having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has a maximum cross-sectional dimension transverse to

the mid-longitudinal axis (Fig. 5), is at least in part conical at the leading end and has a flexible member 118 (Specification, page 7, line 6; Fig. 5) at trailing end 120. Flexible member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, and a dimension larger than the maximum cross-sectional dimension of shaft 112. Flexible member 118 is adapted to deform so as to conform to the surface of the tissue in which the rivet is inserted. (Specification, page 6, lines 31-33). The top of flexible member 118 is at least in part concave when flexible member 118 is in contact with the tissue M (Fig. 2; the meniscus is concave (see Exhibit A), thus the top of the flexible member will be concave when in contact with the tissue of the meniscus). Shaft 112 has a plurality of flexible projections 116 (Specification, page 7, lines 2-5; Fig. 5) extending radially from shaft 112. Flexible projections 116 are separate and spaced apart from one another (Fig. 5).

Independent claim 100.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a flexible member 118 proximate trailing end 120 of shaft 112. Flexible member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top, the bottom adapted to contact tissue upon insertion of rivet 100 into the tissue (Fig. 7). Flexible member 118 is at least in part curved when the bottom of flexible member 118 contacts the tissue. (Fig. 2; the meniscus is curved (see Exhibit A), thus the flexible member will be curved when in contact with the tissue of the meniscus).

Independent claim 144.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a

mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a flexible member 118 proximate trailing end 120 of shaft 112. Flexible member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top, the bottom adapted to contact tissue upon insertion of rivet 100 into the tissue (Fig. 7). At least a portion of the bottom of flexible member 118 forms an included angle relative to the mid-longitudinal axis of shaft 112 that is greater than 90 degrees. (Fig. 7; see also Exhibit D, angle A).

Independent claim 176.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a flexible member 118 proximate trailing end 120 of shaft 112. Flexible member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top that is adapted to contact tissue. (Fig. 7). Flexible member 118 has an outer perimeter between the top and the bottom (Fig. 5), at least a portion of the outer perimeter being flexible relative to shaft 112 when rivet 100 is inserted into the tissue. (Specification, page 6, lines 31-33; Figs. 6-7).

Independent claim 211.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8)

and a bottom (Fig. 5) opposite the top, and an outer perimeter, the bottom being adapted to contact tissue upon insertion of rivet 100 into the tissue (Fig. 7). At least a first portion of the bottom adjacent to the outer perimeter is at an acute angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle A), at least a second portion of the bottom adjacent to the outer perimeter is at an obtuse angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle B).

Independent claim 242.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top that is adapted to contact tissue. (Fig. 7). At least a portion of member 118 is moveable relative to shaft 112 between an undeployed position where the bottom surface is not in contact with the tissue (Fig. 6) and a deployed position where the bottom surface contacts the tissue (Fig. 7). Member 118 has a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape. (Figs. 6-7).

Independent claim 273.

The present invention in another preferred embodiment is directed to a method for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together with a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5). The method comprises the step of providing rivet 100 having a shaft 112 with a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, a mid-longitudinal axis (Specification, page 7, line 7) therebetween, and a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, the bottom being adapted to contact tissue (Fig. 7). At least a

portion of member 118 is moveable relative to shaft 112 between an undeployed position where the bottom surface is not in contact with the tissue (Fig. 6) and a deployed position where the bottom surface contacts the tissue (Fig. 7), the member having a first shape in the deployed position (Fig. 6) and a second shape in the undeployed position (Fig. 7), the first shape being different from the second shape (Figs. 6-7). The method also includes the steps of inserting rivet 100 into the tissue until the bottom contacts the tissue (Specification, page 7, lines 27-29; Figs. 6-7); and moving at least a portion of the member relative to the shaft to the deployed position (Specification, page 7, lines 29-31; Fig. 7).

Independent claim 283.

The present invention in another preferred embodiment is directed to a method for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together with a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5). The method comprises the step of providing rivet 100 having a shaft 112 with a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a flexible member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top. The method also comprises the steps of engaging a driving instrument 130 to rivet 100 (Specification, page 7, lines 21-23; Figs. 5-6); and inserting rivet 100 into the tissue until the bottom of flexible member 118 contacts the tissue (Specification, page 7, lines 27-29) and flexible member 118 deforms to conform to the curvature of the tissue adjacent 100 rivet (Specification, page 7, lines 29-31; Figs. 6-7).

Independent claim 293.

The present invention in another preferred embodiment is directed to a method for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together with a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5). The method comprises the step of providing rivet 100 having a shaft 112 with a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, and an outer perimeter (Fig. 5). The method also includes the step of inserting rivet 100 into the tissue until the bottom of member 118 contacts the

tissue (Fig. 7). At least a first portion of the bottom adjacent to the outer perimeter of member 118 is at an acute angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle A). At least a second portion of the bottom adjacent to the outer perimeter of member 118 is at an obtuse angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle B).

Grounds of Rejection to be Reviewed on Appeal

- I. The amendment filed January 7, 2004 (the "January 2004 Amendment") stands objected to under 35 U.S.C. § 132 for introducing new matter. In particular, the Examiner contends that the phrases listed below and recited in the claims are not supported by the original disclosure.
 - A. "[S]aid flexible member being at least in part curved" (corresponding to item (a) of the objection under 35 U.S.C. § 132 on page 2 of the Final Office Action dated March 19, 2004 (the "March 2004 Office Action").
 - B. "[S]aid flexible member is deformable to have an at least in part concave shape" (corresponding to item (b) of the March 2004 Office Action).
 - C. "[S]aid flexible member has a greater surface area to mass ratio than said shaft" (corresponding to item (c) of the March 2004 Office Action).
 - D. "[S]aid flexible member has a smaller mass than the mass of said shaft" (corresponding to item (d) of the March 2004 Office Action).
 - E. "[A]t least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees" (corresponding to item (i) of the March 2004 Office Action).
 - F. "[A]t least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft" (corresponding to item (k) of the March 2004 Office Action).
 - G. "[A]t least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis" (corresponding to item (l) of the March 2004 Office Action).

II. The specification stands objected to under 35 U.S.C. § 112, first paragraph, as not providing support as originally filed for claims 29-300 (under Ground I, sub-grounds A to G, listed above).

III. Claims 29-300 stand rejected under 35 U.S.C. § 112, first paragraph, as not being adequately described by the specification (under Ground I, sub-grounds A to G, listed above).

IV. Claims 29-300 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

V. Claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,261,914 to Warren ("Warren").

VI. Claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,976,715 to Bays et al. ("Bays") in view of Warren.

VII. Claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren, and further in view of U.S. Patent No. 4,548,202 to Duncan ("Duncan"); U.S. Patent No. 4,728,238 to Chisholm et al. ("Chisholm") or U.S. Patent No. 4,422,276 to Paravano ("Paravano").

VIII. Claims 87, 88, 131, and 132 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bays, Warren, Chisholm, Paravano, and Duncan, and further in view of U.S. Patent No. 4,338,835 to Simons ("Simmons").

Argument

The Appellant submits the following arguments for consideration by the Board of Patent Appeals and Interferences:

I. Objection to the amendment filed January 7, 2004 under 35 U.S.C. § 132.

A. The phrase “said flexible member being at least in part curved” applicable to independent claims 29 and 100.

Appellant discloses that the flexible member is flexible “so as to be able to conform to the angle of the meniscus M,” and “deform so as to conform to the surface of the meniscus.” (Specification, page 6, lines 31-33; and page 7, lines 30-31). It is well known to those skilled in the art of orthopedic surgery that the surface of the meniscus is curved. (See, e.g., Anatomy of the Human Body, Gray Henry, 20th ed., Fig. 349 (1918), a copy of which is attached hereto as Exhibit A). The surgeon installs the rivet of the present invention by inserting the shaft into the tissue of the torn meniscus. After the rivet is fully deployed, the shaft will have penetrated the portions of the meniscus tissue being repaired and the flexible member will be in contact with surface of meniscus. When the flexible member contacts the surface of the meniscus, due to the curvature of the meniscus, the forces between the underside of the flexible member and the tissue of the meniscus cause at least a portion of the perimeter of the flexible member to flex away from the shaft. As a result, at least a portion of the perimeter is elevated relative to the middle of the flexible member overlying the shaft, which is held in place by the shaft. This deformation of the flexible member forms a curve to conform to the curve of the top surface of the meniscus into which the flexible member is inserted. As a result of the deformation, the top surface of the flexible member can become curved to create a concavity in the top surface of the flexible member. Accordingly, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member is “at least in part curved” when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being at least in part curved when in contact with the tissue is inherently supported in the specification and drawings of Appellant’s disclosure as originally filed. According to the MPEP, “[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application *necessarily* discloses that function, theory or advantage, even though it says nothing explicit concerning it.” (MPEP § 2163.07(a), page 2100-184, col. 1 (May 2004)) (emphasis

added). Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground I, sub-ground A as lacking support has been overcome.

For the foregoing reasons, the Examiner's contention in the November 2004 Advisory Action "that the specification states that the flexible member deforms to the surface of the meniscus at an 'angle of the meniscus' not to the curve of the meniscus" is unfounded. (See November 2004 Advisory Action, page 2).

B. The phrase "said flexible member is deformable to have an at least in part concave shape" applicable to claims 33, 105, 148, 183, 214, and 245.

The remarks under item I(A) of the argument above are incorporated by reference herein. Further, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member can have a curved top surface with a shape that is "at least in part concave" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being deformable to have an at least in part concave shape when in contact with the tissue is inherently supported in the specification and drawings of Appellant's disclosure as originally filed. Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground I, sub-ground B as lacking support has been overcome.

C. The phrase "said flexible member has a greater surface area to mass ratio than said shaft" applicable to claims 34, 65, 106, 149, 184, 215, and 246.

The flexible member having a greater surface area to mass ratio than that of the shaft is supported in the original disclosure at least, for example, in Fig. 4. (A copy of Fig. 4 is attached hereto as Exhibit B). The figures can provide support for the claimed invention to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. MPEP § 2163(II)(A)(3)(a) states that "[a]n Appellant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Appellant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, [citation omitted], ("drawings alone may provide a 'written description' of an invention as required by sec. 112"); *In re Wolfensperger*, [citation omitted], (the drawings of Appellant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America v. United*

States, [citation omitted], ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner with the same limitations as the specification.") (MPEP § 2163(II)(A)(3)(a), page 2100-170, col. 2 to page 2100-171, col. 1 (May 2004)).

As shown in Fig. 4, the flexible member has a greater surface area to mass ratio than the shaft. To facilitate the Examiner's understanding of the difference in the surface area to mass ratios, Appellant measured the dimensions of the rivet in Fig. 4 and used these dimensions to calculate their respective ratios. (See Fig. 4, and calculations on page 2 of Exhibit B). In Fig. 4, the surface area to mass ratio of the flexible member is 0.54. The surface area to mass ratio of the shaft is 0.34. Appellant's calculations show, with mathematical certainty, that the flexible member has a greater surface area to mass ratio than the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground I, sub-ground C.

D. The phrase "said flexible member has a smaller mass than the mass of said shaft" applicable to claims 35, 66, 107, 150, 185, 216, and 247.

The remarks under item I(C) of the argument above are incorporated by reference herein. Further, the flexible member having a smaller mass than that of the shaft is supported in the original disclosure at least, for example, in Fig. 4. (See Fig. 4, Exhibit B).

As the flexible member and shaft are made of the same material, it is clear from Fig. 4 that the mass of the flexible member is less than the mass of the shaft. (See Fig. 4, Exhibit B). Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground I, sub-ground D.

E. The phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees" applicable to claim 145.

Appellant respectfully disagrees with the Examiner's contention that the original disclosure does not support a second portion of the bottom of the flexible member forming an included angle relative to the mid-longitudinal axis of the shaft that is less than 90 degrees. An "included angle" is defined as an angle "between or within" two sides. (Merriam Webster's Collegiate Dictionary, 10th ed., page 588, col. 1 (1999); a

copy of page 588 is attached hereto as Exhibit C). Appellant discloses in Fig. 7 an included angle between the bottom of the flexible member and the mid-longitudinal axis of the shaft that is less than 90 degrees. (See angle A as labeled in Fig. 7, a copy of which is attached hereto as Exhibit D).

Appellant respectfully traverses the Examiner's contention that the claim "positively recites that the flexible member is designed with this angle of less than 90 degrees." (November 2004 Advisory Action, page 2). Claim 145 recites that "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis that is less than 90 degrees." (Emphasis added). Appellant respectfully submits that the claim is not limited to a "pre-formed" angle of less than 90 degrees as the Examiner contends, but includes the rivet being deformable to "form" the angle of less than 90 degrees upon insertion into the meniscus. This is clearly supported in Fig. 7. Moreover, the Examiner has agreed that the claimed angle exists "after it [the flexible member] has been deformed during use." (November 2004 Advisory Action, page 2). Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground E.

F. The phrase "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft" applicable to independent claims 211 and 293.

The bottom of the flexible member having a first portion adjacent the perimeter being at an acute angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an acute angle (angle A in Exhibit D) between a first part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground F.

Appellant respectfully traverses the Examiner's contention that the claimed angles "are not properties of the device as made." (November 2004 Advisory Action, page 2). The claimed angles must be a property of the rivet as made, otherwise the rivet would not be able to deform to the angle shown in Fig. 7. Accordingly, Appellant

submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground F.

- G. The phrase "at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft" applicable to independent claims 211 and 293.

The remarks under item I(F) of the argument above are incorporated by reference herein. Further, the bottom of the flexible member having a second portion adjacent the perimeter being at an obtuse angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an obtuse angle (angle B in Exhibit D) between a second part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground G.

Appellant submits that the Examiner's objection to the January 2004 Amendment under 35 U.S.C. § 132 has been overcome.

II. Objection to the specification under 35 U.S.C. § 112, first paragraph, as not supporting the invention as now claimed.

Appellant respectfully submits that the objection to the specification under 35 U.S.C. § 112, first paragraph as not supporting the invention as now claimed is overcome in view of Appellant's remarks addressing the objection to the Amendment filed January 7, 2004 under 35 U.S.C. § 132 above, those remarks being incorporated by reference herein. (See items I(A) to I(G) of the argument above).

III. Rejection of claims 29-300 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not adequately described as set forth in the objection to the specification under Ground I above.

Appellant respectfully submits that the rejection improperly rejects all claims even though many claims do not include the features which the Examiner contends is not supported. In particular, Appellant submits that the features which the Examiner identified as not being adequately supported concern only claims 29-59, 65, 66, 100-143, 145, 148-150, 183-185, 211-241, 245-247, and 293-300. The Examiner has not

provided any rationale as to why claims 60-64, 67-99, 144, 146, 147, 151-182, 186-210, 242-244, and 248-292 are rejected under 35 U.S.C. § 112, first paragraph.

Accordingly, Appellant submits that these claims are allowable despite the Examiner's blanket rejection of all claims. The Examiner's rejection as it concerns claims 29-59, 65, 66, 100-143, 145, 148-150, 183-185, 211-241, 245-247, and 293-300 is addressed below.

A. Claims 29-59 and 100-143 concerning the phrase "said flexible member being at least in part curved" as recited in independent claims 29 and 100.

Appellant discloses that the flexible member is flexible "so as to be able to conform to the angle of the meniscus M," and "deform so as to conform to the surface of the meniscus." (Specification, page 6, lines 31-33; and page 7, lines 30-31). It is well known to those skilled in the art of orthopedic surgery that the surface of the meniscus is curved. (See, e.g., Anatomy of the Human Body, Gray Henry, 20th ed., Fig. 349 (1918), a copy of which is attached hereto as Exhibit A). The surgeon installs the rivet of the present invention by inserting the shaft into the tissue of the torn meniscus. After the rivet is fully deployed, the shaft will have penetrated the portions of the meniscus tissue being repaired and the flexible member will be in contact with surface of meniscus. When the flexible member contacts the surface of the meniscus, due to the curvature of the meniscus, the forces between the underside of the flexible member and the tissue of the meniscus cause at least a portion of the perimeter of the flexible member to flex away from the shaft. As a result, at least a portion of the perimeter is elevated relative to the middle of the flexible member overlying the shaft, which is held in place by the shaft. This deformation of the flexible member forms a curve to conform to the curve of the top surface of the meniscus into which the flexible member is inserted. As a result of the deformation, the top surface of the flexible member can become curved to create a concavity in the top surface of the flexible member. Accordingly, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member is "at least in part curved" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being at least in part curved when in contact with the tissue is inherently supported in the specification and drawings

of Appellant's disclosure as originally filed. According to the MPEP, "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application *necessarily* discloses that function, theory or advantage, even though it says nothing explicit concerning it." (MPEP § 2163.07(a), page 2100-184, col. 1 (May 2004)) (emphasis added). Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground III, sub-ground A as lacking support has been overcome.

B. Claims 33, 105, 148, 183, 214, and 245 concerning the phrase "said flexible member is deformable to have an at least in part concave shape."

The remarks under item III(A) of the argument are incorporated by reference herein. Further, as a result of the deformation of the flexible member against the surface of the meniscus, the top surface of the flexible member becomes curved to create a concavity in the top surface of the flexible member. Accordingly, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member has a top surface with a shape that is "at least in part concave" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being deformable to have an at least in part concave shape when in contact with the tissue is inherently supported in the specification and drawings of Appellant's disclosure as originally filed. Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground III, sub-ground B as lacking support has been overcome.

C. Claims 34, 65, 106, 149, 184, 215, and 246 concerning the phrase "said flexible member has a greater surface area to mass ratio than said shaft."

The flexible member having a greater surface area to mass ratio than that of the shaft is supported in the original disclosure at least, for example, in Fig. 4. (See Fig. 4, Exhibit B). The figures can provide support for the claimed invention to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. MPEP § 2163(II)(A)(3)(a) states that "[a]n Appellant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Appellant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, [citation omitted], ("drawings alone may provide a 'written description' of an

invention as required by sec. 112"); *In re Wolfensperger*, [citation omitted], (the drawings of Appellant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America v. United States*, [citation omitted], ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner with the same limitations as the specification.") (MPEP § 2163(II)(A)(3)(a), page 2100-170, col. 2 to page 2100-171, col. 1 (May 2004)).

As shown in Fig. 4, the flexible member has a greater surface area to mass ratio than the shaft. To facilitate the Board's understanding of the difference in the surface area to mass ratios, Appellant measured the dimensions of the rivet in Fig. 4 and used these dimensions to calculate their respective ratios. (See Fig. 4, and calculations on page 2 of Exhibit B). In Fig. 4, the surface area to mass ratio of the flexible member is 0.54. The surface area to mass ratio of the shaft is 0.34. Appellant's calculations show, with mathematical certainty, that the flexible member has a greater surface area to mass ratio than the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground III, sub-ground C.

D. Claims 35, 66, 107, 150, 185, 216, and 247 concerning the phrase "said flexible member has a smaller mass than the mass of said shaft."

The remarks under item III(C) of the argument are incorporated by reference herein. Further, as the flexible member and shaft are made of the same material, it is clear from Fig. 4 that the mass of the flexible member is less than the mass of the shaft. (See Fig. 4, Exhibit B). Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground III, sub-ground D.

E. Claim 145 concerning the phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees."

Appellant respectfully disagrees with the Examiner's contention that the original disclosure does not support a second portion of the bottom of the flexible member forming an included angle relative to the mid-longitudinal axis of the shaft that is less than 90 degrees. An "included angle" is defined as an angle "between or within" two sides. (Merriam Webster's Collegiate Dictionary, 10th ed., page 588, col. 1 (1999); Exhibit C). Appellant discloses in Fig. 7 an included angle between the bottom of the

flexible member and the mid-longitudinal axis of the shaft that is less than 90 degrees. (See angle A as labeled in Fig. 7, Exhibit D). Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground III, sub-ground E.

- F. Claims 211-241 and 293-300 concerning the phrase "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft" as recited in independent claims 211 and 293.

The bottom of the flexible member having a first portion adjacent the perimeter being at an acute angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an acute angle (angle A in Exhibit D) between a first part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground III, sub-ground F.

- G. Claims 211-241 and 293-300 concerning the phrase "at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis" as recited in independent claims 211 and 293.

The bottom of the flexible member having a second portion adjacent the perimeter being at an obtuse angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an obtuse angle (angle B in Exhibit D) between a second part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground III, sub-ground G.

Appellant submits that the Examiner's rejection of claims 29-300 under 35 U.S.C. § 112, first paragraph for failing to provide support for the invention as now claimed has been overcome.

IV. Rejection of claims 29-300 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.

Appellant respectfully submits that this rejection is improper because the Examiner's rationale for supporting the rejection relates to issues of inadequate written support and not to indefiniteness, which is an issue under 35 U.S.C. 112, first paragraph, not second paragraph.

Moreover, Appellant respectfully submits that the Examiner has again improperly rejected all claims when the features identified by the Examiner as allegedly lacking support are not applicable to all claims. In particular, the features identified by the Examiner as allegedly lacking support concern only claims 29-59, 72, 73, 75, 95, 100-143, 145, 148, 156, 158, 173, 183, 191, 193, 208, 211-241, 245, 253, 255, 270, and 293-300 as they existed before the entry of the September 2004 Amendment. The Examiner has not provided any rationale as to why claims 60-71, 74, 76-94, 96-99, 144, 146, 147, 149-155, 157, 159-172, 174-182, 184-190, 192, 194-207, 209, 210, 242-244, 246-252, 254, 256-269, and 271-292 are rejected under 35 U.S.C. § 112, second paragraph. Accordingly, Appellant submits that these claims are allowable despite the Examiner's blanket rejection of all claims. The Examiner's rejection as it concerns claims 29-59, 72, 73, 75, 95, 100-143, 145, 148, 156, 158, 173, 183, 191, 193, 208, 211-241, 245, 253, 255, 270, and 293-300 is addressed below.

A. Claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 concerning the phrase "along the mid-longitudinal axis."

In order to expedite prosecution, Appellant amended claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 in the September 2004 Amendment to change "along" to "around" as indicated by the Examiner as being supported in the disclosure as originally filed. (See March 2004 Office Action, page 3, last full paragraph). The amendment was entered by the Examiner. (November 2004 Advisory Action). The claims now recite that the projections are oriented in arrays "around the mid-longitudinal axis of said shaft." Accordingly, Appellant submits that the rejection of claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 has been overcome.

- B. Claims 43, 75, 117, 158, 193, 224, and 255 concerning the phrase "at least two of said projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft."

Appellant respectfully disagrees with the Examiner's contention that the original disclosure does not support at least two flexible projections extending from the shaft in the same plane transverse to the mid-longitudinal axis of the shaft. Appellant discloses at least two flexible projections *extending* from the shaft in the same plane in Fig. 1. A copy of Fig. 1 is attached hereto as Exhibit E with a transverse plane drawn thereon showing two of the flexible projections extending from the shaft along a plane "P."

Moreover, Appellant notes that the Examiner's position in the March 2004 Office Action is inconsistent with the Examiner's earlier position stated in the Office Action dated July 7, 2003. In that Office Action, the Examiner stated that "[i]t would appear in all of the drawings the projections all extend in the same perpendicular plane. Therefore there are always four projections in a plane perpendicular to the longitudinal axis." (Office Action dated July 7, 2003, page 4, paragraph 2). Appellant submits that the disclosure as originally filed supports at least two of the flexible projections extending from the shaft in the same plane transverse to the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the rejection of claims 43, 75, 117, 158, 193, 224, and 255 has been overcome.

- C. Claims 56, 95, 139, 173, 208, 239, and 270 concerning the rivet being approximately 10 mm in length.

In order to expedite prosecution, Appellant amended claims 56, 95, 139, 173, 208, 239, and 270 in the September 2004 Amendment to change "10 mm" to "8 mm," which is supported in the specification on page 8, line 4. The amendment was entered by the Examiner. (November 2004 Advisory Action). Accordingly, Appellant submits that the rejection of claims 56, 95, 139, 173, 208, 239, and 270 has been overcome.

- D. Claims 29-59 and 100-143 concerning the flexible member being at least in part curved (recited in independent claims 29 and 100); claims 33, 105, 148, 183, 214, and 245 concerning the flexible member being at least in part concave; and claims 145, 211-241, and 293-300 concerning the member being at an angle not perpendicular to the mid-longitudinal axis.

Appellant submits that the rejection of claims 29-59, 100-143, 145, 148, 183, 211-241, 245, and 293-300 are overcome based on Appellant's remarks addressing the

Examiner's rejection of these claims under 35 U.S.C. § 112, first paragraph above, these remarks being incorporated by reference herein. (See items III(A), III(B), III(E), III(F), and III(G) of the argument above).

Appellant submits that the rejection of claims 29-300 under 35 U.S.C. § 112, second paragraph, as being indefinite has been overcome.

V. The rejection of claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,261,914 to Warren ("Warren").

A. Arguments applicable to all claims under the current rejection: the Examiner's rationale for supporting the rejection in view of Warren is inconsistent with the teachings of Warren.

1. The structure of the head taught by Warren cannot be ignored.

The Examiner states that "[d]ue to the fact that the rivet of Warren is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that [the] rivet of Warren would comprehend the claimed resilient characteristic at least to some extent." (March 2004 Office Action, paragraph bridging pages 4 and 5). By focusing only on the material of the Warren fastener, the Examiner is ignoring the structure of the fastener taught by Warren. Warren teaches that head 110 has a thickness greater than the wall thickness of the shank. (See Warren, col. 3, lines 38-40, 46, and 47; col. 4, lines 66-67). The thickness of the shank wall is obtained by subtracting the rib diameter, 0.157 inches, from the diameter of the internal bore, 0.048 inches, and then dividing the result by two to arrive at 0.0545 inches, which is less than the 0.069 inch thickness of the head. If the head of the Warren fastener were flexible enough to deform to conform to the surface of the tissue as recited, for example, in claims 29 and 60, then shank of the Warren fastener would have insufficient rigidity to withstand repeated blows to be driven into the bone. This result follows because the head has a thickness greater than the wall of the shank. (See, e.g., Warren, Fig. 1). Thus, if the head were modified to be sufficiently flexible as recited in claims 29 and 60, then the shank would be even more flexible because it is thinner than the head. This, of course, ignores any effect of fillet 161, which as

discussed above would operate to inhibit flexibility. Modifying the head of the Warren fastener as suggested by the Examiner would render the shank of the Warren fastener unsatisfactory for its purpose of being able to be driven into bone or bone-like structures. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-129, col. 2 (May 2004)).

2. The context in which the Warren fastener is used must be considered.

Warren teaches that head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone. (Warren, col. 5, lines 8-16; and Figs. 6-8). The Examiner states that “[t]he only difference between the claims and Warren’s device is that the claims recite that the flexible head member deforms when it is pounded into place. Inherently any head member made of a polymeric material when pounded into place on a surface that is curved or irregular will deform at least to a certain extent.” (March 2004 Office Action, page 5, paragraph bridging pages 4 and 5). First, Appellant’s claims do not recite that the flexible member is “pounded into place.” Second, assuming *arguendo* that there were any deformation of the head of Warren during insertion, such deformation would be due to the repeated striking of the head to pound the fastener into the bone, not due to the resilient nature of the flexible member conforming to the surface of tissue.

The Examiner further states that “[b]ecause different portions of the head will come into contact with the bone at different times the head will deform as one portion of the head cannot move and other portions continue to move closer to the bone.” (March 2004 Office Action, page 5, paragraph bridging pages 4 and 5). Appellant respectfully submits that the Examiner is ignoring the context in which Warren teaches using the fastener. Warren teaches driving the fastener through ligament 200 and into bone 300. (Warren, col. 5, lines 13-14; Figs. 7 and 8). As the fastener is pounded into the bone, the head “captivates the ligament against the bone.” (Warren, col. 5, lines 15-16). The head taught by Warren is not designed to be used against bone, but rather “ligaments or ligament-like objects.” (Warren, col. 7, lines 28-29). As the head of the Warren fastener is pounded in, it will contact the softer ligament. Thus, any deformation as between the head and the ligament will be confined to the ligament deforming, not the

head. To attempt to use the fastener of Warren to attach only bone segments together would change the principal operation of the Warren fastener. The Examiner's modification of the principal of operation of the Warren fastener is not permissible. (See MPEP § 2143.01, "The Proposed Modification Cannot Change the Principle of Operation of a Reference," page 2100-132, col. 1 (May 2004)).

3. The Examiner's redesign of the Warren fastener is without teaching or suggestion.

The Examiner states that "Warren teaches that the fastener can be thinner." (March 2004 Office Action, page 5, paragraph bridging pages 5 and 6). The Examiner then redesigns the Warren fastener to fit within the scope of Appellant's claimed invention. (See March 2004 Office Action, paragraph bridging pages 5 and 6). The Examiner states that a thinner fastener "would then result in a head member that would flex as it is forced into contact with the bone," and that finding the right dimensions "would result in a head that flexes during implantation." (March 2004 Office Action, paragraph bridging pages 5 and 6). Appellant respectfully submits that the Examiner's redesign of the Warren fastener is improper. First, the Examiner has not provided any motivation as to why one would modify the Warren fastener to have "a head that flexes." (March 2004 Office Action, page 6, paragraph bridging pages 5 and 6) (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)). Second, modifying the Warren fastener as suggested by the Examiner render it unsuitable for its intended purpose of being able to be pounded into bone as taught by Warren. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-131, col. 2 (May 2004)). Accordingly, the Examiner's proposed redesign of the Warren fastener cannot be applied in the rejection.

4. The Examiner is using impermissible hindsight.

Appellant also submits that the Examiner is using impermissible hindsight in order to fashion a motivation to support the rejection. The Examiner states that "it would have been obvious to modify the rivet of Warren" to have "a head that flexes." (March 2004 Office Action, page 6, paragraph bridging pages 5 and 6). Such a motivation is not suggested in the art cited by the Examiner. In the specification,

Appellant teaches a flexible member that is “sufficiently flexible so as to be able to conform to the angle of the meniscus.” (Specification, page 6, lines 31-33). Appellant submits that prior to Appellant’s teachings, there was no motivation to have a head that flexes.

It is respectfully submitted that the Examiner is using impermissible hindsight by gleaning the motivation used to reject the present claims over Warren from Appellant’s own teachings in the specification. (See MPEP § 2141.01(III), page 2100-121, col. 2 (May 2004) (“[i]t is difficult but necessary that the decision-maker forget what he or she has been taught...about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.” (citation omitted)). Appellant respectfully submits that the rejection was not framed with the mind of one skilled in the art presented only with the references and then-commonly accepted wisdom in the art, but with the guidance of Appellant’s teachings. It is therefore submitted that a *prima facie* case of obviousness has not been established.

B. Arguments applicable to separately grouped claims.

1. Claims 29-31, 33-37, and 44-52.

Warren teaches away from the claimed invention. Warren discloses a surgical fastener for attaching soft tissues to bone or bone-like structures. (Warren, col. 7, lines 22-31). In order to insert the fastener into the bone, Warren teaches that head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone. (Warren, col. 5, lines 8-16; and Figs. 6-8). Accordingly, the structure of head 110 must be able to withstand repeated blows to drive the fastener into bone.

Warren discloses two ways that the head is made sufficiently rigid to withstand pounding. First, head 110 is made thick. Warren teaches that the thickness of head 110 is 0.069 inches, which is more thick than any part of the shank wall 115 perpendicular to the longitudinal axis of the fastener. (Warren, col. 3, lines 38-40; Fig. 1). Secondly, Warren teaches the use of a fillet 161 at the junction of shank portion 115 and lower surface 160 of head 110. (Warren, col. 3, lines 40-42). As is

known in the art, fillets are used to reinforce a corner where two surfaces meet. (See, e.g., Merriam Webster's Collegiate Dictionary, 10th ed., page 435, col. 1 (1999); a copy of page 435 is attached hereto as Exhibit F). Accordingly, the head of the Warren fastener is rigid in order to withstand repeated pounding so that the fastener can be driven into bone.

Independent claim 29 recites a tissue rivet having a flexible member at the trailing end, the flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and being "at least in part curved when said flexible member is in contact with the tissue." As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part curved when in contact with tissue as recited in claim 29.

Not only does Warren not teach or suggest a rivet as recited in claim 29, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 29 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 29.

2. Claim 32.

Appellant further submits that the cited art, whether alone or in proper combination, fails to teach or suggest the subject matter of claim 32. Claim 32 recites the flexible member having an outer edge that is beveled. In the March 2004 Office Action, the Examiner contends that "making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art." (March 2004 Office Action, page 6, paragraph 1).

Pursuant to MPEP 2144.03(c), Appellant challenged the Examiner's assertion that the skin rubbing over the head of a tissue fastener is a well-recognized problem in the art that is solved by making the heads flush. (See MPEP 2144.03(c), "[i]f Appellant challenges a factual assertion as not properly Officially Noticed or not properly based upon common knowledge, the Examiner must support the finding with adequate evidence," page 2100-138, col. 1 (May 2004)). First, the skin of a patient makes no contact with a trailing end of a rivet that is inserted into the meniscus of the knee. The

flexible member of the rivet taught by Appellant is configured to minimize interference with normal knee-joint motion, not skin abrasion. Second, none of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, a flexible member having a beveled outer edge. (See, e.g., Bays, Fig. 3; Warren, Fig. 8; and Duncan, Fig. 9). Also, according to the MPEP, “[i]f the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2).” (MPEP 2144.03(c), page 2100-138, col. 1 (May 2004)).

In the November 2004 Advisory Action, the Examiner failed to provide the evidence requested by Appellant in accordance with MPEP § 2144.03(c). Accordingly, Appellant submits that the rejection of claim 32 should be withdrawn.

3. Claims 60-63, 65-69, 76-86, and 95-99.

Independent claim 60 recites the flexible member being adapted to “deform so as to conform to the surface of the tissue in which said rivet is inserted,” and the top of the flexible member being “at least in part concave when said flexible member is in contact with the tissue.” As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part concave as recited in claim 60.

Not only does Warren not teach or suggest a rivet as recited in claim 60, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 60 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant’s claimed invention because its head is not flexible as recited in independent claim 60.

4. Claim 64.

Claim 64 recites the flexible member having an outer edge that is beveled. In the March 2004 Office Action, the Examiner contended that “making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art.” (March 2004 Office Action, page 6, paragraph 1).

In accordance with MPEP 2144.03(c), Appellant challenged the Examiner's assertion. (See remarks concerning claim 32 above (item V(B)(2) of the argument), which are incorporated by reference herein). In the November 2004 Advisory Action, the Examiner failed to provide the evidence requested by Appellant in accordance with MPEP § 2144.03(c). Accordingly, Appellant submits that the rejection of claim 64 should be withdrawn.

5. Claims 100-103, 105-111, 114, 115, 118-130, and 139-143.

Independent claim 100 recites the flexible member being "at least in part curved when said bottom of said flexible member contacts the tissue." As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part curved when in contact with tissue as recited in claim 100.

Not only does Warren not teach or suggest a rivet as recited in claim 100, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 100 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 100.

6. Claim 104.

Claim 104 recites the flexible member having an outer edge that is beveled. In the March 2004 Office Action, the Examiner contended that "making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art." (March 2004 Office Action, page 6, paragraph 1).

In accordance with MPEP 2144.03(c), Appellant challenged the Examiner's assertion. (See remarks concerning claim 32 above (item V(B)(2) of the argument), which are incorporated by reference herein). In the November 2004 Advisory Action, the Examiner failed to provide the evidence requested by Appellant in accordance with MPEP § 2144.03(c). Accordingly, Appellant submits that the rejection of claim 104 should be withdrawn.

7. Claims 144-153, 156, 159-167, and 173-175.

Independent claim 144 recites at least a portion of the bottom of the flexible member "forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees." Warren teaches a fastener with a head having a bottom that is perpendicular to the mid-longitudinal axis of the shank. (See Warren, Fig. 8). Warren does not teach or suggest a tissue rivet having the angular relationship as recited in independent claim 144.

Not only does Warren not teach or suggest a rivet as recited in claim 144, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 144 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 144.

8. Claims 176-188, 191, 194-202, and 208-210.

Independent claim 176 recites the flexible member having an outer perimeter, "at least a portion of said outer perimeter being flexible relative to said shaft when said rivet is inserted into the tissue." The head taught by Warren is not configured for moving or flexing, at least due to the greater thickness of the head relative to the shank, and fillet 161 as discussed above. (See, e.g., Warren, Fig. 1). Warren does not teach or suggest a tissue rivet as recited in independent claim 176.

Not only does Warren not teach or suggest a rivet as recited in claim 176, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 176 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 176.

9. Claim 192.

Dependent claim 192 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." Warren does not teach or suggest such a configuration. Moreover, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 192. Therefore, it is

submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 192 under 35 U.S.C. § 103(a) is improper and must be withdrawn.

10. Claims 211-219, 222, 225-233, and 239-241.

Independent claim 211 recites a member having a bottom, "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft, at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft." Warren teaches a fastener with a head having a bottom that is perpendicular to the mid-longitudinal axis of the shank. (See Warren, Fig. 8). Warren does not teach or suggest a tissue rivet having the angular relationship as recited in independent claim 211.

Not only does Warren not teach or suggest a rivet as recited in claim 211, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 211 by using a head design that must be perpendicular to the longitudinal axis of the shank to facilitate the insertion of the fastener by repeated pounding. (See Warren, Figs. 6-8). If the head of the Warren fastener were angled as recited in claim 211, repeatedly striking the head as taught by Warren to insert the fastener would be made more difficult because a portion of the vertical insertion force would be translated laterally and the fastener would be more difficult to insert. Accordingly, Appellant submits that Warren teaches away from Appellant's claimed invention. (See MPEP §2141.02, "Prior Art Must Be Considered In Its Entirety, Including Disclosures That Teach Away From The Claims," page 2100-127, col. 1 (May 2004)).

11. Claims 242-250, 253, 256-264, and 270-272.

Independent claim 242 recites a member, "at least a portion of said member being moveable relative to said shaft between an undeployed position where said bottom surface is not in contact with the tissue and a deployed position where said bottom surface contacts the tissue, said member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape." The head taught by Warren is not configured for moving or flexing, at least due to the greater thickness of the head relative to the shank, and fillet 161 as discussed above. (See, e.g., Warren, Fig. 1). Warren does not teach or

suggest a tissue rivet as recited in independent claim 242.

Not only does Warren not teach or suggest a rivet as recited in claim 242, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 242 using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not moveable as recited in independent claim 242.

12. Claims 273-276, 278, 279, and 282.

Independent claim 273 recites a method for holding pieces of tissue together, including the steps of providing the rivet with a member having a bottom, "at least a portion of the member being moveable relative to the shaft between an undeployed position where the bottom surface is not in contact with the tissue and a deployed position where the bottom surface contacts the tissue, the member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape," and "moving at least a portion of the member relative to the shaft to the deployed position." Warren teaches driving the fastener into the bone and so that the head "captivates the ligament against the bone." (Warren, col. 5, lines 15-16; Fig. 8). As shown in Fig. 8 of Warren, when the ligament is "captivated," the bottom of the head remains perpendicular to the mid-longitudinal axis of the shank. Accordingly, Warren does not disclose a method as recited in claim 273.

Not only does Warren not teach or suggest a method as recited in claim 273, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 273 using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not moveable as recited in independent claim 273.

13. Claims 283-285, 289, and 292.

Independent claim 283 recites a method including the step of inserting a rivet into the tissue "until the bottom of the flexible member contacts the tissue and the flexible member deforms to conform to the curvature of the tissue adjacent the rivet." Warren teaches driving the fastener into the bone and so that the head "captivates the

ligament against the bone." (Warren, col. 5, lines 15-16; Fig. 8). As shown in Fig. 8 of Warren, when the ligament is "captivated," the bottom of the head remains perpendicular to the mid-longitudinal axis of the shank. Accordingly, Warren does not disclose a method as recited in claim 283.

Not only does Warren not teach or suggest a method as recited in claim 283, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 283 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 283.

14. Claims 293, 294, 296, 297, and 300.

Independent claim 293 recites a method including the step of inserting a rivet into the tissue "until the bottom of the member contacts the tissue, at least a first portion of the bottom adjacent to the outer perimeter of the member being at an acute angle relative to the mid-longitudinal axis of the shaft, at least a second portion of the bottom adjacent to the outer perimeter of the member being at an obtuse angle relative to the mid-longitudinal axis of the shaft." Warren teaches driving the fastener into the bone and so that the head "captures the ligament against the bone." (Warren, col. 5, lines 15-16; Fig. 8). As shown in Fig. 8 of Warren, when the ligament is "captivated," the bottom of the head remains perpendicular to the mid-longitudinal axis of the shank. Accordingly, Warren does not disclose a method as recited in claim 293.

Not only does Warren not teach or suggest a method as recited in claim 293, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 293 by using a head design that must be perpendicular to the longitudinal axis of the shank to facilitate the insertion of the fastener by repeated pounding. (See Warren, Figs. 6-8). If the head of the Warren fastener were angled as recited in claim 293, repeatedly striking the head as taught by Warren to insert the fastener would be made more difficult because a portion of the vertical insertion force would be translated laterally and the fastener would be more difficult to insert. Accordingly, Appellant submits that Warren teaches away from Appellant's claimed invention. (See MPEP § 2141.02, "Prior Art Must Be Considered In Its Entirety, Including Disclosures That

"Teach Away From The Claims," page 2100-127, col. 1 (May 2004)).

Appellant submits that independent claims 29, 60, 100, 144, 176, 211, 242, 273, 283, and 293 are patentable over Warren and that dependent claims 30-37, 44-52, 61-69, 76-86, 95-99, 101-111, 114, 115, 118-130, 139-143, 145-153, 156, 159-167, 173-175, 177-188, 191, 192, 194-202, 208-210, 212-219, 222, 225-233, 239-241, 243-250, 253, 256-264, 270-272, 274-276, 278, 279, 282, 284, 285, 289, 292, 294, 296, 297, and 300 are patentable over Warren at least because they depend from an allowable independent claim, or claims dependent therefrom.

Appellant submits that the rejection of claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 under 35 U.S.C. § 103 as being unpatentable over Warren has been overcome.

VI. The rejection of claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,976,715 to Bays et al. ("Bays") in view of Warren.

A. Arguments applicable to all claims under the current rejection.

1. The motivation used by the Examiner to support the combination of references is unsupportable.

Bays teaches a tack member 10 for repairing damaged tissue, a hollow applicator 20, and a needle 30 slidably receivable in applicator 20 and tack member 10. (See Bays, col. 4, line 67 through col. 5, line 5). Applicator 20 has a J-shaped configuration at its forward end 21 (see Bays, Fig. 1) which serves to restrain a grip portion 15 of the tack member. (Bays, col. 5, lines 5-18).

The Examiner contends that "it would have been obvious to modify the rivet of Bays as taught by Warren to find the desired dimensions of a specific intended use that would be thin enough resulting in a head that flexes during implantation." (March 2004 Office Action, page 7, paragraph 1). Appellant respectfully submits that this motivation is unsupportable because it does not state why one of ordinary skill in the art would want to modify the head of Bays to flex. (See MPEP § 2143.01, "the Prior Art Must

Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)). Accordingly, Appellant respectfully submits that the rejection is unsustainable and must be withdrawn.

2. The combination of Bays and Warren teach away from Appellant's claimed invention.

Even assuming *arguendo*, that there was proper motivation to combine the repair tack of Bays with the fastener of Warren, the combination teaches away from Appellant's claimed invention. The J-configuration of the Bays applicator serves to restrain the head portion "against twisting or rotation about any axis extending vertically." (Bays, col. 5, lines 16 and 17). In order to serve its intended purpose, the head portion adapted to be used with the applicator of Bays must be sufficiently rigid enough to withstand axial movement and withstand twisting or rotation. Appellant submits that if head 110 of the Warren fastener has the sufficient rigidity for use with the J-configuration of the applicator of Bays, then the proposed combination would not render Appellant's claimed invention obvious since a fastener head that is rigid enough to withstand axial movement and twisting or rotation about any vertical axis cannot be fairly said to be sufficiently flexible within the scope of Appellant's claimed invention.

B. Arguments applicable to separately grouped claims.

1. Claims 29-31, 33-37, 40, 41, and 44-59.

Even if the combination of Bays and Warren could be properly maintained, Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant. Both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member at the trailing end, the flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and being "at least in part curved when said flexible member is in contact with the tissue" as recited in independent claim 29.

2. Claim 32.

Dependent claim 32 recites the flexible member having an outer edge that is beveled. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest such a configuration. (See, e.g., Bays, Fig. 3; and Warren, Fig. 8). Moreover, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 32. Therefore, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 32 under 35 U.S.C. § 103(a) is improper and must be withdrawn.

3. Claims 60-63, 65-69, 72, 73, 76-86, and 89-99.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 60. As stated above in item V(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and the top of the flexible member being "at least in part concave when said flexible member is in contact with the tissue" as recited in independent claim 60.

4. Claim 64.

Dependent claim 64 recites the flexible member having an outer edge that is beveled. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest such a configuration. (See, e.g., Bays, Fig. 3; and Warren, Fig. 8). Moreover, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 64. Therefore, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 64 under 35 U.S.C. § 103(a) is improper and must be withdrawn.

5. Claims 100-103, 105-111, 114, 115, 118-130, and 133-143.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 100. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective

insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member being "at least in part curved when said bottom of said flexible member contacts the tissue" as recited in independent claim 100.

6. Claim 104.

Dependent claim 104 recites the flexible member having an outer edge that is beveled. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest such a configuration. (See, e.g., Bays, Fig. 3; and Warren, Fig. 8). Moreover, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 104. Therefore, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 104 under 35 U.S.C. § 103(a) is improper and must be withdrawn.

7. Claims 144-153, 156, and 159-175.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 144. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member where at least a portion of the bottom of the flexible member forms "an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees" as recited in independent claim 144.

8. Claims 176-188, 191, and 194-210.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 176. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member having an outer perimeter, "at least a portion of said outer perimeter being flexible relative to

said shaft when said rivet is inserted into the tissue" as recited in independent claim 176.

9. Claims 211-219, 222, and 225-241.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 211. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a member having a bottom, "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft, at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft" as recited in independent claim 211.

10. Claims 242-250, 253, and 256-272.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 242. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a member, "at least a portion of said member being moveable relative to said shaft between an undeployed position where said bottom surface is not in contact with the tissue and a deployed position where said bottom surface contacts the tissue, said member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape" as recited in independent claim 242.

11. Claims 273-276, 278-280, and 282.

Appellant submits that the combination does not teach or suggest a method as claimed by Appellant in independent claim 273. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper

combination, teach or suggest a method including the steps of providing the rivet with a member having a bottom, "at least a portion of the member being moveable relative to the shaft between an undeployed position where the bottom surface is not in contact with the tissue and a deployed position where the bottom surface contacts the tissue, the member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape," and "moving at least a portion of the member relative to the shaft to the deployed position" as recited in independent claim 273.

12. Claim 277.

Dependent claim 277 recites the method step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. The fastener of Warren is pounded into position. (Warren, col. 5, lines 8-16). The repair tack assembly of Bays is assembled by first "placing the cross bar portion 15 into slot 23 at the forward end of applicator 20," and then needle 30 is "slidably passed through the hollow applicator and bore 13 in tack member 10." (Bays, col. 6, lines 25-29). Accordingly, Appellant submits that claim 277 is allowable over the cited art.

13. Claim 281.

Dependent claim 281 recites the method step of "inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Appellant submits that claim 281 is allowable over the cited art.

14. Claims 283-285, 289, 290, and 292.

Appellant submits that the combination does not teach or suggest a method as claimed by Appellant in independent claim 283. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a method including the step of inserting a rivet into the

tissue "until the bottom of the flexible member contacts the tissue and the flexible member deforms to conform to the curvature of the tissue adjacent the rivet." Warren teaches driving the fastener into the bone and so that the head "captivates the ligament against the bone" as recited in independent claim 283.

15. Claims 286 and 287.

Dependent claim 286 recites the method step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. The fastener of Warren is pounded into position. (Warren, col. 5, lines 8-16). The repair tack assembly of Bays is assembled by first "placing the cross bar portion 15 into slot 23 at the forward end of applicator 20," and then needle 30 is "slidably passed through the hollow applicator and bore 13 in tack member 10." (Bays, col. 6, lines 25-29). Accordingly, Appellant submits that claims 286 and 287 are allowable over the cited art.

16. Claim 288.

Dependent claim 288 recites the step of "snap-fitting the rivet onto a portion of the driving instrument." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Appellant submits that claim 288 is allowable over the cited art.

17. Claim 291.

Dependent claim 291 recites the method step of "inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Appellant submits that claim 291 is allowable over the cited art.

18. Claims 293, 294, 296-298, and 300.

Appellant submits that the combination does not teach or suggest a method as claimed by Appellant in independent claim 293. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper

combination, teach or suggest a method including the step of inserting a rivet into the tissue "until the bottom of the member contacts the tissue, at least a first portion of the bottom adjacent to the outer perimeter of the member being at an acute angle relative to the mid-longitudinal axis of the shaft, at least a second portion of the bottom adjacent to the outer perimeter of the member being at an obtuse angle relative to the mid-longitudinal axis of the shaft" as recited in independent claim 293.

19. Claim 295.

Dependent claim 295 recites the method step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. The fastener of Warren is pounded into position. (Warren, col. 5, lines 8-16). The repair tack assembly of Bays is assembled by first "placing the cross bar portion 15 into slot 23 at the forward end of applicator 20," and then needle 30 is "slidably passed through the hollow applicator and bore 13 in tack member 10." (Bays, col. 6, lines 25-29). Accordingly, Appellant submits that claim 295 is allowable over the cited art.

20. Claim 299.

Dependent claim 299 recites the method step of "inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Appellant submits that claim 299 is allowable over the cited art.

Appellant notes that the remarks above pertaining to claims 277, 281, 286-288, 291, 295, and 295 were presented in the September 2004 Amendment. The November 2004 Advisory Action did not present any arguments refuting Appellant's position. Accordingly, Appellant's position on these claims stands unchallenged.

Appellant submits that independent claims 29, 60, 100, 144, 176, 211, 242, 273, 283, and 293 are patentable over Warren and Bays and that dependent claims 30-37, 40, 41, 44-59, 61-69, 72, 73, 76-86, 89-99, 101-111, 114, 115, 118-130, 133-143, 145-153, 156, 159-175, 177-188, 191, 194-210, 212-219, 222, 225-241, 243-250, 253, 256-272, 274-282, 284-292, and 294-300 are patentable over Warren at least because they

depend from an allowable independent claim, or claims dependent therefrom.

Appellant submits that the rejection of claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 under 35 U.S.C. § 103 as being unpatentable over Bays in view of Warren has been overcome.

VII. The rejection of claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren, and further in view of U.S. Patent No. 4,548,202 to Duncan (“Duncan”); U.S. Patent No. 4,728,238 to Chisholm et al. (“Chisholm”) or U.S. Patent No. 4,422,276 to Paravano (“Paravano”).

A. Arguments applicable to all claims under the current rejection.

Appellant submits that Chisholm and Paravano are non-analogous art. The claims of the present invention are directed to a surgical tissue rivet and methods of surgery. Chisholm is directed to a plastic drive fastener for use in the automotive industry. (Chisholm, col. 2, lines 22-26). In particular, Chisholm states that “[t]he importance of the present invention relates to a plastic drive fastener which can be readily installed into an apertured panel or a bore within a thick panel in which the removal force is far in excess of the force of installation.” (Chisholm, col. 2, lines 22-31). Paravano relates to “[a] door trim fastener assembly [that] includes a headed fastener overlying the backing layer of a trim panel and having a shank which extends through a slot in the trim panel.” (Paravano, Abstract). Appellant states in the background of the specification that rivet-like tabs used in the automotive industry are “relatively large and have no application in a surgical procedure.” (Specification, page 3, lines 18-20).

Appellant submits that the surgical field and the automotive field are non-analogous fields of endeavor and therefore cannot be combined to arrive at Appellant's claimed invention. (See MPEP § 2141.01(a), “Analogy in the mechanical arts,” page 2100-123, cols. 1 and 2 (May 2004), which discusses *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992)(“The court held the reference was not within the field of Appellant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or

motivated to look to fasteners for garments.”). Accordingly, Appellant submits that the rejection is unsustainable and must be withdrawn. Appellant notes that Chisholm was also cited in the Office Action dated July 11, 1994, but was successfully overcome after Appellant’s reply dated March 17, 1995 in which Chisholm was asserted as being non-analogous art.

Appellant submits that even if Chisholm and Paravano are not included in the proposed combination of references to reject the claims under 35 U.S.C. 103(a), the rejections over claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 are rendered moot at least because they depend from an allowable independent claim, or claims dependent therefrom.

Appellant notes that the above remarks were presented in the September 2004 Amendment. The November 2004 Advisory Action did not present any arguments refuting Appellant’s position. Accordingly, Appellant’s position stands unchallenged.

B. Arguments applicable to separately grouped claims.

1. Claim 42.

Appellant’s remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 29 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(1) of the argument above). Further, dependent claim 42 recites a plurality of projections “positioned in a radially staggered configuration along said shaft.”

None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being “equally spaced about the periphery of each leg.” (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster’s Collegiate Dictionary, defines the term “stagger” as “marked by an alternating or overlapping pattern.” (Merriam-Webster’s Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 42 is allowable over the analogous cited art.

2. Claim 74.

Appellant’s remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 60 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(2) of the argument above). Further, dependent claim 74 recites a

plurality of projections “positioned in a radially staggered configuration along said shaft.” None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being “equally spaced about the periphery of each leg.” (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster’s Collegiate Dictionary, defines the term “stagger” as “marked by an alternating or overlapping pattern.” (Merriam-Webster’s Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 74 is allowable over the analogous cited art.

3. Claim 116.

Appellant’s remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 100 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(3) of the argument above). Further, dependent claim 116 recites a plurality of projections “positioned in a radially staggered configuration along said shaft.” None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being “equally spaced about the periphery of each leg.” (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster’s Collegiate Dictionary, defines the term “stagger” as “marked by an alternating or overlapping pattern.” (Merriam-Webster’s Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 116 is allowable over the analogous cited art.

4. Claim 157.

Appellant’s remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 144 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(4) of the argument above). Further, dependent claim 157 recites a plurality of projections “positioned in a radially staggered configuration along said shaft.” None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being “equally spaced about the periphery of each leg.” (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster’s Collegiate Dictionary,

defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 157 is allowable over the analogous cited art.

5. Claim 192.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 176 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(5) of the argument above). Further, dependent claim 192 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 192 is allowable over the analogous cited art.

6. Claim 223.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 211 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(6) of the argument above). Further, dependent claim 223 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 223 is allowable over the analogous cited art.

7. Claim 254.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 242 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(7) of the argument above). Further, dependent claim 254 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 254 is allowable over the analogous cited art.

Appellant submits that the rejection of claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren, and further in view of Duncan, Chisholm, or U.S. Paravano has been overcome.

VIII. The rejection of claims 87, 88, 131, and 132 under 35 U.S.C. § 103(a) as being unpatentable over Bays, Warren, Chisholm, Paravano, and Duncan, and further in view of U.S. Patent No. 4,338,835 to Simons ("Simmons").

A. Arguments applicable to all claims under the current rejection: the alleged equivalent must be an art recognized equivalent.

Bays teaches a hollow applicator 20, a needle 30 slidably receivable in applicator 20, and tack member 10. (Bays, col. 4, line 67 through col. 5, line 5). Applicator 20 has a J-shaped configuration at its forward end 21 (Bays, Fig. 1) which serves to restrain a grip portion 15 of the tack member. (Bays, col. 5, lines 5-18). Simmons teaches a driver 10 having a driver head 16 with four curved convex surfaces 22. (Simmons, col. 2, lines 49-57; Figs. 1 and 4). Simmons does not teach or suggest that driver head 16 is equivalent to the needle and J-shaped applicator combination of Bays. The Examiner states that "it would have been obvious to one of ordinary skill in

the art to further modify the prior art to use a spherical recess and cooperating driver as taught by Simmons as an obvious equivalent way of mating the driver to the fastener to force the fastener into place." (March 2004 Office Action, page 8, paragraph 2).

According to the MPEP, "[i]n order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on Appellant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents." (MPEP § 2144.06, page 2100-144, cols. 1 and 2 (May 2004), citing *In re Ruff*, 256 F.2d 590 (CCPA 1958)). Since Simmons fails to teach that his driver head is equivalent to the applicator configuration taught by Bays, the driver taught by Simmons cannot be cited as an obvious equivalent.

Appellant notes that the above remarks were presented in the September 2004 Amendment. The November 2004 Advisory Action did not present any arguments refuting Appellant's position. Accordingly, Appellant's position stands unchallenged.

B. Arguments applicable to separately grouped claims.

1. Claim 87.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 60 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(3) of the argument above). Even if, assuming *arguendo*, the driver head of Simmons were an applicable mechanical equivalent, none of the art cited by the Examiner, whether alone or in proper combination, teach or suggest a tissue rivet having a shaft with a trailing end that includes a depression that is configured to cooperatively engage a driver instrument, as recited in claim 87. Simmons teaches a flat-headed machine screw 32 with four concave curved surfaces 38. (Simmons, col. 3, lines 12-16; Fig. 3). The machine screw taught by Simmons is not suitable for use as a tissue rivet in a surgical environment. Accordingly, Appellant submits that the rejection in view of Simmons is unsubstantiated and must be withdrawn.

2. Claim 88.

Appellant's remarks in item VIII(B)(1) of the argument above are incorporated by reference herein. Even if, assuming *arguendo*, the driver head of Simmons were an applicable mechanical equivalent, none of the art cited by the Examiner, whether alone or in proper combination, teach or suggest a tissue rivet having a shaft with a trailing

end that includes a depression that is at least in part spherical as recited in claim 88. Simmons teaches a flat-headed machine screw 32 with four concave curved surfaces 38. (Simmons, col. 3, lines 12-16; Fig. 3). The machine screw taught by Simmons is not suitable for use as a tissue rivet in a surgical environment. Accordingly, Appellant submits that the rejection in view of Simmons is unsubstantiated and must be withdrawn.

3. Claim 131.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 100 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(3) of the argument above). Even if, assuming *arguendo*, the driver head of Simmons were an applicable mechanical equivalent, none of the art cited by the Examiner, whether alone or in proper combination, teach or suggest a tissue rivet having a shaft with a trailing end that includes a depression that is configured to cooperatively engage a driver instrument, as recited in claim 131. Simmons teaches a flat-headed machine screw 32 with four concave curved surfaces 38. (Simmons, col. 3, lines 12-16; Fig. 3). The machine screw taught by Simmons is not suitable for use as a tissue rivet in a surgical environment. Accordingly, Appellant submits that the rejection in view of Simmons is unsubstantiated and must be withdrawn.

4. Claim 132.

Appellant's remarks in item VIII(B)(3) of the argument above are incorporated by reference herein. Even if, assuming *arguendo*, the driver head of Simmons were an applicable mechanical equivalent, none of the art cited by the Examiner, whether alone or in proper combination, teach or suggest a tissue rivet having a shaft with a trailing end that includes a depression that is at least in part spherical as recited in claim 132. Simmons teaches a flat-headed machine screw 32 with four concave curved surfaces 38. (Simmons, col. 3, lines 12-16; Fig. 3). The machine screw taught by Simmons is not suitable for use as a tissue rivet in a surgical environment. Accordingly, Appellant submits that the rejection in view of Simmons is unsubstantiated and must be withdrawn.

Appellant submits that the rejection of claims 87, 88, 131, and 132 under 35 U.S.C. § 103(a) as being unpatentable over Bays, Warren, Chisholm, Paravano, and

Duncan, and further in view of Simons has been overcome.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: April 21, 2005

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 6/17/5

Application Number: 08/354,450

Filing Date: 12 December 1994

Appellant(s): Gary Karlin Michelson, M.D.

MAILED

Group 3700

Todd M. Martin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 20 April 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(8) ClaimsAppealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

| | | |
|-----------|-----------------|---------|
| 5,261,914 | Warren | 11-1993 |
| 4,976,715 | Bays et al. | 12-1990 |
| 4,548,202 | Duncan | 10-1985 |
| 4,728,238 | Chisholm et al. | 03-1988 |

| | | |
|-----------|----------|---------|
| 4,422,276 | Paravano | 12-1983 |
| 4,338,835 | Simons | 7-1982 |

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

The amendment filed 07 January 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in the claims it is recited that

- a) said flexible member being at least in part curved
- b) said flexible member is deformable to have an at least in part concave shape
- c) said flexible member has a greater surface area to mass ratio than said shaft
- d) said flexible member has a smaller mass than the mass of said shaft
- e) at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees
- f) at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft
- g) at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft.

Regarding a), appellant is attempting to claim how the flexible member deforms during use as a positive structural limitation of the device when not in use. The claims recite "said flexible member being at least in part curved when said flexible member is in contact with the tissue" (claim 29 lines 10-11 for example). It is not clear how much weight can be given this

language since this curved shape is not disclosed. Does that mean the flexible member is formed in part curved in order to be curved when in contact with tissue? Is it made out of a specific material that provides this function. Appellant is now relying patentability on limitation however, it is not clear from the specification what would comprehend this language. It is not clear how this would define over the art since the art teaches the same structure using the same material.

The same would apply to issue b). Requiring "said flexible member is deformable to have an at least in part concave shape" (claim 33, for example) is a limitation that requires a specific shape however, it is not clear how much weight to give this language since it is not disclosed.

Regarding c), appellant is claiming "said flexible member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member" (claim 34, for example). Appellant has also provided some detailed calculations on how they came up with this claim language. It is not clear how much weight can be given this claim limitation since it is not disclosed in the written description. Appellant is basing these detailed limitations from the drawings however, the drawings are not drawn to scale. Such detailed measurements and calculations cannot be clearly ascertained to such a detailed degree.

Regarding d), while the drawing may support that fact that the flexible member is smaller than the shaft (claim 35, for example), there is no support in the written description for this limitation and why it is now critical to the patentability of the invention. This function of being

absorbed prior to the shaft so that the flexible member does not separate from the shaft is not fully understood because it is not disclosed.

Regarding e), claim 145, for example, recites “at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees.” This time this limitation is not contingent on when the device is in use. This is a positive structural limitation of the device before use. There is nothing in the written description clearly setting forth this claim limitation and the drawings do not support this. Appellant points to figure 7 to provide support for this limitation however, this drawing shows an intended use where the device is inserted at an angle into the tissue. What if the intended use was not inserted at an angle but rather at right angles to the tissue surface? Then the bottom surface of the flexible member would not have an included angle less than 90 degrees. Then would this limitation not exist if the intended use included being inserted at a right angle to the tissue? Moreover, this is the only limitation in a dependent claim. How does this claim further limit the parent claim? What further structural limitation is now being recited that somehow further limits the structure already recited? The parent claim 144 recites the first portion of the flexible member forms an included angle greater than 90 degrees that likewise is not contingent on when the device is in use. Likewise this limitation is not supported by the disclosure as originally filed.

Regarding f), the same argument above for e) would apply to the language of claim 211 for example, “at least a first portion of the said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft”. The bottom of “a member” is

not formed at an acute angle relative to the axis of the shaft as disclosed. It may form the angle in intended use however, that is contingent on how it is used.

Regarding g), the same argument above for e) would apply to the language of claim 211, for example, "at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft".

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

There appears to be no support in the specification for the above noted claim language or the criticality why this is now being claimed.

Claims 29-300 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 29-300 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the metes and bounds of the claims are since the claim language noted above has no clear support in the specification as originally filed. For example, it is not clear how much weight can be given the language that the flexible member forms an acute angle relative to the longitudinal axis of the shaft since the device is not made that way. There is no

disclosure for the flexible head member being formed at an acute angle to the shaft. The angle the flexible head makes with the shaft is dependent on how it is placed in the body.

Claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, 300 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren.

Warren discloses the same surgical rivet arrangement as that claimed by appellant. He discloses that the rivet has a hollow shaft and a number of flexible projections extending from said shaft and the flexible head member at the other end. He also discloses that the rivet is made of biodegradable material, copolymers of glycolide, the same material used by appellant. Warren also teaches that the material is intended to be resilient such that the projections deform upon insertion (column 6, lines 1-6). Warren teaches the heart of appellant's invention.

The claimed curvature, concave shape, acute angle, obtuse angle that the flexible head makes describes how it deforms during use. The thickness of the Warren's head is approximately 0.069 inches, column 3, line 38. Such a thin head would allow the flexible member to flex during use. Moreover, Warren teaches column 6, lines 46-49, "the dimensions of the fastener could be changed so as to make the fastener longer and thinner, or shorter and fatter, etc." The only difference between the claims and Warren would appear to be dimensions or sizes of the different parts and how it flexes during use. Due to the fact that the rivet of Warren has all of the basic main structural features and is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that the rivet of Warren would comprehend the claimed resilient characteristic as disclosed. The head of

Warren would appear to be flexible to conform to the shape of the tissue to which it is being forced into.

Appellant appears to be attempting to define the instant invention over the prior art by claiming how the rivet is deformed during use. Warren teaches that the specific dimensions and sizes of the different parts of the rivet can be modified to fit a particular intended use. There appears to be no unobviousness to change the dimensions of the rivet to find the optimum characteristics for a particular intended use. As suggested by Warren different dimensions can be used dependent on practical considerations of intended use. Making the head of the fastener less obtrusive so that it is flush with the tissue surface so that the head does not interfere with any surrounding tissue is a well-recognized problem in the art. Reducing the size of the head would provide a smooth continuous surface, thereby insuring that nothing would be caught on the extending rivet head and be damaged. Making the head of screws, rivets and the like flush has always been a problem solved through routine experimentation. To any extent it is felt that the head of Warren is not flexible to conform to the shape of the surrounding tissue, it would have been obvious to one of ordinary skill in the art to modify Warren to change dimensions of the flexible member to reduce the amount of material used or reduce the size of the flexible head to make it less obtrusive.

Claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, 256-300 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bays et al. in view of Warren.

Bays teaches another fastener that has all of the claimed structure including being made out of the same material as the instant invention and intended to repair torn meniscus tissue. For

the same reasons above, it is not clear how the claimed invention would define over Bays other than how it deforms during use. The thickness of the Bays flexible head member is 0.025 inches. Even thinner than Warren's. Bays also teaches "It is to be understood, of course, that variations from these dimensions are possible for different utilizations of the tack member 10" column 7, lines 15-17. It would appear that the head of Bays would curve or flex when the rivet is pressed against the tissue to deform to match the same shape of the tissue at least to some extent. As noted above, the specific dimensions of the rivet are well within the realm of the artisan of ordinary skill. It would appear that the flexible member of Bays would result in a flexible head member that would flex and conform to the shape of the tissue as it is being forced into to the tissue. To any extent it is felt that the head of Bays is not flexible, it would have been obvious to one of ordinary skill in the art to modify Bays to find the optimum dimensions as also suggested by Warren to providing a flexible head to make the head less obtrusive and more flexible so that it is flush with the surrounding tissue.

Claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above and further in view of Duncan, Chisholm et al. or Paravano.

There is no unobviousness to the specific shape or number of ribs on the shaft of the rivet. Both Bays and Warren teach that the specific configuration of the ribs is well within the artisan of ordinary skill. Warren teaches column 7, lines 3+ "that surgical fastener 100 might be formed with more or less ribs 135 than the three ribs shown in FIGS. 1-8. Thus, for example, a surgical fastener 100A having eight ribs 135A is shown in FIGS. 9-11." Bays teaches column 4, lines 62-64, "As few as one and more than three barb members may be provided within the scope

of the present invention, so long as the barb member or members provide sufficient resistance to rearward movement of the shaft portion through the cartilaginous tissue.” Duncan, Chisholm and Paravano are all cited to show different conventional alternative arrangements of ribs on the shafts of fasteners. Duncan teaches a surgical fastener that has barbs that are spaced in plural arrays around the axis of the shaft. Chisholm and Paravano also exemplify the art of providing plural arrays of barbs or fins spaced around the axis of the shaft. It would have been obvious to one of ordinary skill in the art to further modify the prior art to arrange the ribs, fins or barbs in arrays around the axis of the shaft as taught by Duncan, Chisholm or Paravano to provide the desired level of anchorage for the fastener to hold it in place.

Claims 87, 88, 131, 132 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above, and further in view of Simons.

There appears to be no unobviousness to exactly how the rivet interfaces with the driving element. Any conventional configuration to interface the driving element with the head of the rivet would have been obvious. The problem of keeping the engagement between the driving element and the rivet is old. The driving element merely has to drive the rivet into the bone and keep engagement with the rivet. Warren teaches a hollow driver 600 that buts the end of the rivet to force the rivet into the hole in the bone. Bays teaches a driver that includes a shaft that mates with a passageway within the rivet. There is no unobviousness to how the driver forces the rivet into the bone. Simons teaches another equivalent way for the driver to mate with the head of the fastener. The fastener includes a generally spherical recess in the head. It would have been obvious to one of ordinary skill in the art to further modify the prior art to use a

spherical recess and cooperating driver as taught by Simons as an obvious equivalent way of mating the driver to the fastener to force the fastener into place.

(11) Response to Argument

Regarding the issue of new matter under paragraph a) above, Appellant argues that the instant invention is flexible and thereby has disclosed the claimed limitation of "being at least in part curved when said flexible member is in contact with the tissue". Appellant is arguing that this limitation defines over the prior art because of the prior art relative sizes shown in the drawings are not the same dimensions shown in the drawings of the instant application. It order to interpret the scope of the claimed invention one has to look toward the specification to find the breadth and meaning of the language used in the claims. In order to find how the claimed flexible head member defines over the flexible head member of the prior art one has to look to the specification of the instant invention. Is this curved flexible member a result of what the flexible head is made out of? Is it specific dimensions. The specification appears silent with regard to how one is know how the instant invention is different from the prior art. The prior art teaches all of the positive structural limitations including the type of material used. But somehow the prior art head is different from the instant invention head. It can't be because of the type of material used because they are both made out of the same material. The thickness of the head of Warren is 0.069 inches and the thickness of the head of Bays is 0.025 inches. How much thinner would the head of the prior art have to be in order to anticipate the claimed invention? How exactly is the prior art different from the instant invention? It is not clear from the specification exactly what structural limitation provides this curved surface when in use.

Reciting that it is curved when it is in contact with the tissue is something that happens during use however, if the location of implantation happens to be on a flat section of tissue then the head would not deform so then how would one know if the invention in their hand anticipates the claimed invention?

Regarding paragraph b), Appellant argues that the flexible member is “deformable to have an at least in part concave shape when in contact with the tissue is inherently supported in the specification and drawings of Appellant’s disclosure as originally filed.” As noted above it is not clear what structural limitation or characteristic of the disclosed invention the claimed limitation is referring to since the prior art teaches everything claimed. Particularly since this language is found in a dependent claim 33 further limiting the curved shape recited in claim 29. What further limitation from the curved shape provides this added limitation that makes it concave? Moreover, this is the only limitation in the dependent claim so it is not clear how this claim further defines the invention as set forth in claim 29. What new or additional feature over what has already been claimed does this new claim provide? The specification doesn’t appear to provide such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

Regarding paragraph c), Appellant is now reciting a specific structural relationship “wherein said flexible member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member”. There is no support in the invention as disclosed for such a limitation. Appellant is relying on the drawings to provide support for this feature. Appellant argues that it may be sufficient to show possession of an invention by disclosure of drawings that are sufficiently detailed to show

that Appellant was in possession of the claimed invention as a whole. This is generally true for structure or elements sufficiently detailed to show possession of the claimed invention however, it is the examiner's position that the details that Appellant is now relying patentability on are of such minor differences that the drawings cannot be relied upon to teach the patentable limitation. The differences are a matter of degree and not the overall existence of structure. This is not a matter of whether or not the drawings show a claimed element but rather mathematical calculation of relative dimensions based on drawings that are not drawn to scale. If this limitation is of such critical importance that patentability depends on such a limitation, why doesn't the written description provide at least a hint of such a limitation?

Regarding paragraph d), the same arguments above for extracting dimensions from the drawings would apply here as well.

Regarding paragraph e), the limitation that a second portion of the bottom of the flexible member forms an included angle relative to the mid-longitudinal axis of the shaft is greater than 90 degrees in claim 145 is not contingent on when the flexible member is in contact with tissue. Therefore this is a positive structural limitation of the device before use. This is clearly not supported by the specification as originally filed. Appellant relies on figure 7 to support this claim however, this figure shows the device when inserted at an angle in the tissue. The flexible member does not naturally form this included angle. It is only in intended use and only when the device is being inserted at an angle to the surface of the tissue. According to these claims, if the device were inserted at a right angle to the surface of the tissue then the flexible member would be at an angle to the surface of the tissue when in contact with the tissue. The flexible member would not be flush with the surface of the tissue.

Regarding paragraphs f) and g), the same argument above in paragraph e) would apply here as well. The claimed acute and obtuse angle the member makes relative to the shaft is not contingent on intended use and would appear to be inaccurate since the device as disclosed does not have this limitation naturally. Only in intended use does this angle exist however, these claims require this angle as a positive structural limitation.

Regarding the objection to the specification under 35 U.S.C. 112 first paragraph, the examiner respectfully submits that the objection to the specification is proper in view of the arguments given above.

Regarding the rejection of claims 29-300 under 35 U.S.C. 112 first paragraph as containing subject matter that is not adequately supported by a clear and complete disclosure is proper in view of the arguments give above.

Appellant states that the examiner has not provided any rationale as to why claims 60-64, 67-99, 144, 146, 147, 151-182, 186-210, 242-244 and 248-292 are rejected under 35 U.S.C. 112 first paragraph. These claims also contain the offensive language and fall within the paragraphs above. For example, claim 60 is an independent claim that recites the flexible member being at least in part concave when said flexible member is in contact with the tissue and therefore falls with paragraph b) above. Claims 61-64 and 67-99 depend on claim 60 and therefore include all the limitations of claim 60 and likewise not supported by a clear and complete disclosure. Claim 144 recites at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees and therefore falls with paragraph e) above.

Regarding claims 29-59 and 100-143 concerning the phrase "said flexible member being at least in part curved", Appellant argues that during use the flexible member will flex and conform to the shape of the tissue. This is all well and good however, this does not further limit the structure of the rivet itself. Applicant is basing patentability on one specific intended use and one specific location. The device is not limited to use in one specific situation. There may be a situation that requires the rivet to be inserted at right angles to the tissue and therefore it is not clear how the claims would define over the prior art in this instance because the flexible member would have flexed.

Regarding claims 33, 105, 148, 183, 214, and 245, the same arguments above would apply here as well. It is not clear how much weight can be given the functional intended use claim language.

Regarding claims 34, 65, 106, 149, 184, 215 and 246, as noted above the drawings are not drawn to scale, therefore it is not clear how much weight can be given these detailed measurements drawn from them.

Regarding claims 35, 66, 107, 150, 185, 216 and 247, the same arguments of the drawings are not drawn to scale as noted above would apply here as well.

Regarding claim 145, the same arguments above given to functional intended use language applies here as well.

Regarding claims 211-241, the same arguments above given to functional intended use language applies here as well.

Regarding the rejection of claims 29-300 under 35 U.S.C. 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Appellant regards as the invention. Since the claims recite claim language that is not clearly supported by the specification with sufficiency to determine the scope of the claim, the claims are vague and indefinite.

Appellant's arguments under paragraph IV subparagraphs A-C are moot in view of the amendment entered in 20 September 2004.

Regarding Appellant's arguments under paragraph V subparagraph A1, contrary to Appellant's assertion that the examiner is focusing only on the material of the Warren fastener to teach the claimed invention, the examiner is instead relying on the full disclosure of Warren to provide the heart of Appellant's invention. Not only does Warren teaches all of the positive structural limitations of the rivet including a shaft, a truncated conical penetration leading end, a flexible member at the trailing end and a plurality of flexible projections extending radially from the shaft but it is also made of the same material. The only difference is whether or not the flexible member being at least in part curved when the flexible member is in contact with the tissue. It is not clear how much weight can be given this claim language since it contingent on intended use of the device. This limitation is only true when the flexible member is in contact with the human tissue. Plus this limitation is also contingent on whether or not the rivet is being inserted at an angle to the tissue surface. Should the rivet be inserted at right angles to the tissue surface then the flexible member would not curve, be concave or have an included angle other than 90 degrees. The flexible member would stay in its natural form of being perpendicular to the shaft.

Regarding Appellant's arguments that the dimensions of Warren would preclude flexing of the head of Warren, the thickness of the head of Warren is 0.069 inches. It is obvious to one

of ordinary skill in the art that a head that is only 0.069 inches in thickness would allow the head to flex and conform to the shape of the surface of the tissue.

Moreover Warren teaches that the dimensions of the fastener can be changed to make the fastener thinner or thicker. It can be longer or shorter. Warren is not limited to just the embodiment shown in the drawings. Finding the optimum dimensions and characteristics for a specific intended use would be well within the realm of the artisan of ordinary skill. Making the head of the fastener less obtrusive so that it is flush with the tissue surface is a well-recognized problem in the art. Reducing the size of the head would provide a smooth continuous surface, thereby insuring that nothing would be caught on the extending rivet head and be damaged. Making the head of screws, rivets and the like flush has always been a problem solved through routine experimentation. If it is felt that the head of Warren would not conform to the shape of the tissue then it would have been obvious to one of ordinary skill in the art to modify Warren to change dimensions of the fastener such as to reduce the amount of material used or to reduce the size of the flexible head to make it less obtrusive.

It is not clear what specific limitations would have to be taught in order to anticipate the functional intended use language claimed. The only difference between the prior art and the perceived claim limitations is specific dimensions of the flexible head member. If 0.069 inches is not thin enough to be flexible then what dimension would be? There appears to be no unobviousness to finding the optimum size and dimensions of the prior art device for a specific intended use as suggested by the prior art. Moreover, there doesn't appear to be unexpected results which is different in kind and not merely in degree from the results of the prior art.

Regarding Appellant's arguments under paragraph V subparagraph A2, Appellant states that Warren teaches that the head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone and that the instant invention is not pounded into place. The instant invention is also intended to be used to attach soft tissue to bone (page 4, lines 29-30) therefore it is not clear what the difference is. If the prior art and the instant invention are intended for the same purpose then how is it different? Appellant is again arguing over how the device is intended to be used. Appellant's specification may not recite that it is pounded into place however it is connected to a driver and driven into place some how. The prior art is also driven into place using the same type of driver.

Regarding Appellant's arguments under paragraph V subparagraph A3, Appellant argues that the examiner's redesign of Warren is without teaching or suggestion. Warren already teaches the thickness of the head is only 0.069 inches which would result in a head that would be flexible. This inherent flexibility would comprehend the claim language. However, to any extent it is felt that the head of Warren is no flexible enough the examiner is using the teaching of the prior art to modify the dimensions of the fastener if needed. It is not clear if Warren even needs to be modified however, if it does Warren himself teaches such a modification. Column 6, lines 47-49, of Warren teaches that the dimensions of the fastener can be changed as desired. Making the head of the fastener less obtrusive so that it is flush with the tissue surface is a well-recognized problem in the art. Reducing the size of the head would provide a smooth continuous surface, thereby insuring that nothing would be caught on the extending rivet head and be damaged. If necessary reducing the size of the head as much as possible to make the head less obtrusive would have been an obvious provision.

Regarding Appellant's arguments under paragraph V subparagraph A4, Appellant argues that the examiner is using impermissible hindsight. As noted in the paragraph above, it is believed that the head of Warren already is flexible however, it would have been obvious to modify Warren to change the dimensions of the head or shaft for any desired specific intended use as taught by Warren. The modification is not impermissible hindsight. The prior art suggests such changes may be necessary.

Regarding Appellant's arguments under paragraph V subparagraph B1, Appellant argues that the head of Warren is repeatedly struck in order to drive fastener 100 through the tissue into bone. Accordingly, the structure of head 110 must be able to withstand repeated blows to drive the fastener into bone. Even though Appellant has extrapolated the relative dimensions of the thickness of the head in relation to the thickness of the shank wall and recited the use of fillet 161 it still doesn't preclude one of ordinary skill in the art to vary the dimensions of the head and shank as desired and still be able to drive the fastener into bone. The driver of Warren provides the required structural rigidity to facilitate driving and inserting the fastener into bone. The driver supports the entire outer surface of the head and provides the required structural support to the head to drive the fastener into the bone. The shaft of the driver received within the hollow shank of the fastener also provides the required structural rigidity to the shank to maintain the integrity of the shank to drive the fastener into the bone.

Appellant's arguments that if Warren's head were modified to be thinner than the thickness of the shank it would destroy the fastener are unsupported. The driver provides the required stability to the fastener to withstand the forces applied to insert the fastener to the bone. If Appellant's arguments were true the Appellant's invention wouldn't work either because the

instant invention is also intended to be inserted into bone just as Warren's. Appellant's invention is "to provide a device which can be used generally to attach soft tissue to bone" page 4 lines 29-30.

Regarding Appellant's arguments in paragraph V subparagraphs B2, B4, B6, the claims require that the outer edge of the flexible member be beveled. Warren already teaches this limitation as shown in the drawings. The outer edge of the flexible member is rounded or beveled as shown in the drawings.

Regarding Appellant's arguments in paragraph V subparagraph B3, B5, B7, B8, B10, B11, B12, B13, B14 the same reasons recited above regarding the flexibility of the head of Warren would apply here as well. The head would conform to the shape of the tissue to some extent including being concave if the shape of the tissue is concave.

Regarding Appellant's arguments in paragraph V subparagraph B9, Duncan teaches the plurality of projections in radially staggered configuration as claimed and would have been an obvious provision in Warren. There is no unobviousness to the exact shape of the projections as long as they prevent removal of the fastener.

Regarding Appellant's arguments in paragraph VI subparagraph A1, Appellant states that there is no suggestion to modify Bays to change the dimensions of the device. The examiner respectfully disagrees since Bays teaches "It is to be understood, of course, that variations from these dimensions are possible for different utilizations of tack member 10". The prior art teaches the motivation for modifying the dimensions of the rivet. Different intended uses requires appropriate changes to the dimensions of the rivet. It is not inventive to discover the optimum or

workable ranges by routine experimentation. There are no unexpected results by changing the dimensions of the rivet as noted above.

Bays teaches the thickness of the head is 0.025 inches which is smaller than the thickness of the head of Warren. How thin does the head have to be to anticipate the claimed invention?

Regarding Appellant's arguments in paragraph VI A2, it is not clear how much weight can be given the arguments that the applicator 20 of Bays must be sufficiently rigid enough to withstand axial movement and withstand twisting or rotation. This has nothing to do with the rejection. The claims do not define over the applicator 20 of Bays. Bays is not being modified regarding the applicator 20. Warren is merely cited to teach the same thing that Bays already teaches i.e., that variations in the dimensions of the rivets is well known to the artisan of ordinary skill. The only difference between the claims and Bays is Appellant's arguments of how the device deforms during use. It is maintained that the prior art devices would deform during use and if it is felt that the rivet of Bays somehow does not deform then Warren additionally is cited to teach the convention of being able to change the relative dimensions of the rivet dependent on practical considerations of intended use.

Regarding Appellant's arguments in paragraph VI subparagraph B1, as noted above the heads of Bays and Warren can withstand being inserted by the insertion tool because the insertion tool contacts and holds the head of the fastener firmly in place and transfers the forces directly to the shaft of the fastener just as Appellant's invention does. The head also still has the ability to conform to the shape of the tissue because of the sizes and any variation of size is well within the realm of the artisan of ordinary skill.

Regarding Appellant's arguments in paragraph VI subparagraph B2, B4, B6, the outer edge of head of Bays is also rounded or beveled comprehending the claim limitations.

Regarding Appellant's arguments in paragraph VI subparagraph B3, B5, B7, B8, B9, B10, B11, B14, B18, the same arguments give above in item V(B)(1) would apply here as well.

Regarding Appellant's arguments in paragraph VI subparagraph B12, B15, B19, Appellant argues that the prior art does not teach driving the rivet until the face of the driving instrument contacts the top of the member. It is not clear how Appellant can disregard the teaching of the prior art. Figure 1 of Bays clearly shows the driving instrument in contact with the top of the member. Figure 7 of Warren clearly teaches the driving instrument in contact with the top of the member.

Regarding Appellant's arguments in paragraph VI subparagraph B13, B17, B20, and claims 281, 291 attaching the meniscus to the bone isn't always inserting the leading end of the shaft toward the center of the knee. Repairing torn meniscus is never always going to be directed toward the center of the knee.

Regarding Appellant's arguments in paragraph VI subparagraph B16, the fastener of Bays is friction fit within the J-shaped arms 26 of the insertion member. There is no unobviousness to the head being friction fit or snap fit in place. Such is well within the realm of the artisan of ordinary skill.

Regarding claims 277, 286-288, 295, the rivet passageway cooperating with the shaft extending from the handle of the insertion instrument is clearly taught by both Bays and Warren and as noted in the previous paragraph. The rejection is maintained.

Regarding Appellant's arguments in paragraph VII subparagraph A, the references to Chisholm and Paravano are cited to teach different shapes and arrangements of the projecting members. In the art of providing projecting members along the shaft of fasteners to solve the problem of holding the fastener in place preventing inadvertent removal is the same across different arts. Both Warren and Bays teach that the number and location of the projections on their fasteners can be varied dependent on intended use. Someone solving the problem of finding other equivalent alternative configurations of the projecting members to prevent the fastener from coming out of the hole would look to other fasteners not necessarily restricted to the medical art.

Bays and Warren already teach projections that are spaced apart form one another along the mid-longitudinal axis of said shaft. Duncan, which is in the medical field, teaches projections that are spaced apart along and around the mid-longitudinal axis of the shaft. The projections are in at least four arrays along and around the shaft. They are radially staggered at 90 degree intervals.

Regarding Appellant's arguments in paragraph VII subparagraph B1, B2, B3, B4, B5, B6, B7, Duncan teaches projections that are in staggered overlapping configuration as they overlap each other along the longitudinal axis of the shaft and are staggered at 90 degree intervals around the shaft. To any extent appellant's projections are staggered so are the projections of Duncan. Appellant's drawings do not appear to show any configuration that is different from what Duncan shows.

Regarding Appellant's arguments in paragraph VIII subparagraph A, B1-B4, Simons teaches a depression in the trailing end of the fastener to mate with the corresponding shaped end

of the insertion member. Simons refers to the depression as "a substantially spherical surface" column 2, lines 62-63. It would have been obvious to one of ordinary skill in the art to further modify the prior art to use a spherical recess and cooperating driver as taught by Simons as an obvious equivalent alternative way of mating the driver to the fastener. In the art of engaging the driver to the head of the fastener one would look to equivalent driver and fastener engagement means. Simons exemplifies an obvious equivalent.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



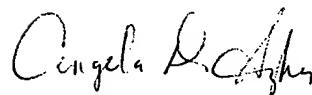
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